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

FORM 10-Q

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

For the quarterly period ended September 30, 2019.

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	**59-3410522**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OGEN	NYSE American

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 [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes [X] 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:

Large accelerated filer	[ ]	Accelerated filer	[ ]
Non-accelerated filer	[X]	Smaller reporting company	[X]
		Emerging growth company	[ ]

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 [X]

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

As of November 8, 2019, there were 46,124,803 shares of Common Stock, $.001 par value, outstanding.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 22,291,924	$ 20,208,301
Prepaid expenses and other current assets	555,465	1,724,975
Total current assets	22,847,389	21,933,276
Property and equipment, net	89,651	116,276
Operating lease right-of-use assets	714,925	—
Total assets	$ 23,651,965	$ 22,049,552
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,894,730	$ 1,043,356
Short-term notes payable	217,419	124,213
Operating lease liabilities	135,120	—
Total current liabilities	2,247,269	1,167,569
Long-term liabilities:		
Operating lease liabilities	586,170	—
Total long-term liabilities	586,170	—
Shareholders' equity:		
Preferred stock, no par value; 50,000,000 shares authorized; 9,417,000 and 9,417,000 Series A shares, 6,600,000 and 6,600,000 Series B shares, 113.941 and 101.733 Series C shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	6,513,396	6,100,182
Common stock, $0.001 par value; 200,000,000 shares authorized; 46,124,803 and 29,433,135 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	46,125	29,433
Additional paid-in capital	138,014,553	126,125,976
Accumulated deficit	(123,755,548)	(111,373,608)
Total shareholders' equity	20,818,526	20,881,983
Total liabilities and shareholders' equity	$ 23,651,965	$ 22,049,552

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 3,067,612	$ 1,580,511	$ 9,360,520	$ 4,178,294
General and administrative	852,841	1,183,830	2,858,997	2,991,300
Total operating expenses	3,920,453	2,764,341	12,219,517	7,169,594
Loss from operations	(3,920,453)	(2,764,341)	(12,219,517)	(7,169,594)
Other income (expense):				
Interest income	86,705	9,066	256,222	15,794
Interest expense	(2,501)	(2,142)	(4,531)	(3,643)
Local business tax	(300)	(418)	(900)	(1,078)
Total other income, net	83,904	6,506	250,791	11,073
Loss before income taxes	(3,836,549)	(2,757,835)	(11,968,726)	(7,158,521)
Income tax benefit	—	—	—	—
Net loss	$ (3,836,549)	$ (2,757,835)	$ (11,968,726)	$ (7,158,521)
Deemed dividend of Series D preferred stock	$ —	$ (1,412,041)	$ —	$ (1,412,041)
Net loss applicable to common shareholders	$ (3,836,549)	$ (4,169,876)	$ (11,968,726)	$ (8,570,562)
Basic and diluted net loss per share	$ (0.08)	$ (0.35)	$ (0.29)	$ (1.12)
Shares used to compute basic and diluted net loss per share	46,124,803	11,937,624	40,989,592	7,656,670

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (11,968,726)	$ (7,158,521)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	44,344	18,393
Stock issued as compensation to non-employee directors	—	24,320
Stock-based compensation expense	542,592	848,612
Stock issued in exchange for services	12,001	6,001
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,442,087	(389,191)
Accounts payable and accrued expenses	851,374	548,510
Net cash used in operating activities	(9,076,328)	(6,101,876)
Cash flows from investing activities:		
Purchase of property and equipment	(11,354)	(60,242)
Net cash used in investing activities	(11,354)	(60,242)
Cash flows from financing activities:		
Payments on short-term notes payable	(179,371)	(134,561)
Net proceeds from issuance of common stock and warrants	11,350,676	1,510,327
Net proceeds from issuance of common stock, convertible preferred stock, and warrants	—	12,431,627
Net cash provided by financing activities	11,171,305	13,807,393
Net increase in cash and cash equivalents	2,083,623	7,645,275
Cash and cash equivalents at beginning of period	20,208,301	6,166,143
Cash and cash equivalents at end of period	$ 22,291,924	$ 13,811,418
Supplemental disclosure of cash flow information:		
Interest paid	$ 4,531	$ 3,643
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ 272,577	$ 244,490
Par value of restricted stock issued	$ —	$ 16
Stock dividend on Series C preferred stock	$ 413,215	$ 58,670
Par value of common stock issued in connection with Series A Preferred Stock Conversion	$ —	$ 259
Value of Series A preferred stock converted into common stock	$ —	$ 268,096
Par value of common stock issued in connection with Series D Preferred Stock Conversion	$ —	$ 7,868
Deemed dividend on Series D preferred stock	$ —	$ 1,412,041
Par value of common stock issued in exchange for services	$ 25	$ 13
Conversion of Series D preferred stock into common stock	$ —	$ 3,750,920

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. 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, 2019 and December 31, 2018 (audited) and three and nine months ended September 30, 2019 and 2018 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, 2019 are not necessarily indicative of the results that may be expected for the year ending December 31, 2019 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, 2018, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2019. 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 incurred a net loss of $11,968,726 and used cash of $9,076,328 in its operating activities during the nine months ended September 30, 2019. As of September 30, 2019, the Company had an accumulated deficit of $123,755,548.

The Company expects to incur substantial expenditures to further develop each of its technologies. The Company believes the working capital at September 30, 2019 will be sufficient to meet the business objectives, as presently structured, through the fourth quarter of 2020. 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 July 2018, the Financial Accounting Standards Board issued Accounting Standards Updates 2018-10 Codification Improvements to Topic 842, Leases and 2018-11 Leases (Topic 842).

Update 2018-10 Codification Improvements to Topic 842 represent changes to clarify the Codification, correct unintended application of guidance, or make minor improvements to the Codification that are not expected to have a significant effect on current accounting practice or create a significant administrative cost to most entities. Some of the amendments make the Codification easier to understand and easier to apply by eliminating inconsistencies, providing needed clarifications, and improving the presentation of guidance in the Codification.

Update 2018-11 Leases (Topic 842) provides entities with an additional (and optional) transition method to adopt the new lease requirements by allowing entities to initially apply the requirements by recognizing a cumulative-effect adjustment transition method, which applies the provisions of the standard at the effective date without adjusting comparative periods presented. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which the entity adopts the new lease requirements would continue to be in accordance with current GAAP (Topic 840). An entity electing this additional (and optional) transition method must provide the required Topic 840 disclosures for all periods that continue to be in accordance with Topic 840. The amendments do not change the existing disclosure requirements in Topic 840. We implemented this standard on January 1, 2019 using the cumulative-effect adjustment transition method, which applies the provisions of the standard at the effective date without adjusting the comparative periods presented. The Company adopted the following practical expedients and elected the following accounting policies related to this standard:

- We did not reassess whether any expired or existing contracts are or contain leases.
- We did not reassess the lease classification for any expired or existing leases.
- We did not reassess initial direct costs for any existing leases.

The standard did not have a material impact on our balance sheets or on our statements of operations. The most significant impact was the recognition of right of use (ROU) assets and lease liabilities for operating leases. We implemented internal controls to enable the preparation of financial information on adoption of the standard. Adoption of the lease standard had no impact to cash provided by or used in operating, financing, or investing activities in the cash flow statements.

In June 2018, the Financial Accounting Standards Board issued Accounting Standards Update 2018-07 Compensation—Stock Compensation (Topic 718) Improvements to Nonemployee Share-Based Payment Accounting. The amendments in this Update expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The requirements of Topic 718 should be applied to nonemployee awards except for specific guidance on inputs to an option pricing model and the attribution of cost (that is, the period of time over which share-based payment awards vest and the pattern of cost recognition over that period). The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, Revenue from Contracts with Customers.

The amendments in this Update are effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. The adoption of this guidance did not have a material impact on the Company's results of operation, financial position or disclosures.

There are no additional accounting pronouncements issued or effective during the three and nine months ended September 30, 2019 that have had, or are expected to have, a material 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 stock based compensation, valuation of warrants, and income tax valuation allowance.

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 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 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 the Company. 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 the Company, 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. In connection with adopting ASU 2016-09, the Company made an accounting policy election to account for forfeitures in compensation expense as they occur.

Warrants

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

Net Loss Per Share

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

Concentrations

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, 2019 and December 31, 2018, the uninsured portion of this balance was $22,041,924 and $19,958,301, respectively.

4. Stock-based Compensation

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

	For the Three Months Ended September 30, 2019	For the Three Months Ended September 30, 2018	For the Nine Months Ended September 30, 2019	For the Nine Months Ended September 30, 2018
Research and development	$ 20,416	$ 73,463	$ 92,503	$ 91,511
General and administrative	211,759	574,839	450,089	781,421
Total Stock-based compensation	$ 232,175	$ 648,302	$ 542,592	$ 872,932

At the Company's Annual Meeting of Shareholders, held on June 20, 2019, the shareholders approved an amendment to the Company's 2012 Equity Incentive Plan (the "Plan") solely to increase the common shares available for awards thereunder by an additional 6,000,000 shares and ratified an amendment approved by shareholders at the prior year's annual meeting to increase the shares available under the Plan by 1,500,000 shares. The aggregate number of shares of the Company's common stock currently authorized pursuant to its Plan, as amended, is 8,250,000 and the Company's Plan, as amended continues to provide that the maximum number of shares that may be subject to stock options and stock appreciation rights granted to any individual in a calendar year is 1,000,000 shares. The Plan also provides that the maximum number of shares that may be subject to awards (other than stock options and stock appreciation rights) intended to qualify as "performance-based compensation" under Section 162(m) of the Internal Revenue Code that may be granted to any individual in one calendar year is 1,000,000 shares (however, the exception for "performance-based compensation" under Code Section 162(m) was repealed in the Tax Cuts and Jobs Act of 2017, unless the awards intended to qualify for such exception were granted before November 2, 2017). As of September 30, 2019, an aggregate of 2,488,293 shares of common stock are covered by outstanding option awards and 5,520,957 shares of common stock are available for future awards under the Plan.

The Company granted -0- and 676,160 stock options under its Plan, with a weighted-average grant date fair value of $-0- and $0.49 per share, during the three and nine months ended September 30, 2019, respectively. The Company granted 1,425,000 and 1,533,000 stock options under its Plan, with a weighted-average grant date fair value of $0.72 and $0.79 per share, during the three and nine months ended September 30, 2018, respectively.

During the nine months ended September 30, 2019, 609,406 stock options previously granted under the Plan vested, no stock options were forfeited, and no stock options were exercised.

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 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 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 Plan.

5. Warrants

On March 25, 2019, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

The offering was comprised of 16,666,668 shares of common stock, together with short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75. The Company granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing.

Each short-term warrant has an exercise price of $0.75 per share of common stock, is immediately exercisable, and will expire on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following the Company's release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and will expire five years following the date of issuance.

A summary of warrant activity for the year ended December 31, 2018 and the nine months ended September 30, 2019 is as follows:

	Warrants	Weighted Average Price
Balance - December 31, 2017	2,177,425	$ 3.10
Granted	14,700,000	1.00
Exercised	(9,505,500)	1.00
Expired	—	—
Balance - December 31, 2018	7,371,925	1.74
Granted	19,166,668	0.83
Exercised	—	—
Expired	—	—
Balance - September 30, 2019	26,538,593	$ 1.08

The warrants outstanding as of September 30, 2019 are as follows:

	Exercise Price	Warrants Outstanding	Expiration Date
	$ 3.10	48,387	9/19/2022
	$ 2.00	900,000	4/10/2023
	$ 3.10	462,106	5/10/2024
	$ 3.10	602,414	7/25/2024
	$ 3.10	1,064,518	11/8/2024
	$ 1.00	4,294,500	7/17/2025
	$ 0.75	9,583,334	9/25/2020*
	$ 0.90	9,583,334	3/25/2024
		26,538,593	

* Subject to termination prior to the indicated date following the Company's release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013 plus twenty-one (21) trading days.

All outstanding warrants are included in shareholders' equity on the Company's Balance Sheets.

6. Short-Term Notes Payable

As of September 30, 2019 and December 31, 2018, the Company had $217,419 and $124,213, respectively, in short-term notes payable for the financing of various insurance policies.

Products Liability Insurance

On March 10, 2019, the Company entered into a short-term note payable for $17,688 bearing interest at 5.69% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being due on February 10, 2020.

On March 10, 2018, the Company entered into a short-term note payable for $28,915 bearing interest at 5.09% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2018 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 12, 2019.

Directors' and Officers' Insurance

On August 7, 2019 the Company entered into a short-term note payable for $254,889 bearing interest at 5.74% 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, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being due on June 24, 2020.

On July 24, 2018, the Company entered into a short-term note payable for $215,575 bearing interest at 5.24% 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, 2018 and were made evenly based on a straight-line amortization over an 11-month period with the final payment being made on June 27, 2019.

7. Commitments and Contingencies

In June 2012, we entered into an Exclusive Channel Collaboration Agreement with Intrexon Corporation ("Intrexon") for the development and commercialization of the native strain of MU1140 and related homologs using Intrexon's advanced transgene and cell engineering platforms (the "Lantibiotic ECC"). In June of 2015, we also entered into an Exclusive Channel Collaboration Agreement with Intrexon and Intrexon Actobiotics NV, (a wholly-owned subsidiary of Intrexon), for the continued development and commercialization of AG013, for use in the treatment of oral mucositis in humans through the administration of an effector via genetically modified bacteria, but, in any case, excluding the delivery of anti-cancer effectors for the purpose of treatment or prophylaxis of cancer which was assigned by Intrexon to its wholly owned subsidiary, ActoBio Therapeutics, Inc. (the "Oral Mucositis ECC"). Intrexon Corporation together with its wholly owned subsidiaries are hereinafter collectively referred to as "Intrexon."

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.

In November of 2017 the Lantibiotic ECC was amended to: (I) consolidate the development milestone payments into one payment of $25,000,000, being due six months after receiving FDA approval of a New Drug Application, (ii) reduce the sublicense revenue percentage we would have had to pay from 50% to 25% of sublicensing revenue, (iii) reduce the royalty rate from 25% of Product Profit to 10% of Net Sales, (iv) revise the form of milestone payments from being share based or cash at the Company's election to only cash, and (v) commit that Diligent Efforts (as defined in the Lantibiotic ECC) in pursuing the Lantibiotic Program would be deemed satisfied in 2018 provided that at least $1,200,000 was budgeted for the advancement of the Lantibiotic Program.

In November of 2017, the Stock Issuance Agreement was also amended. Under the terms of the amendment, the Company has agreed to make certain payments, in cash, to Intrexon upon our achievement of designated milestones. The milestone events and amounts payable are as follows:

(a) a one-time payment of twenty-five million United States dollars ($25,000,000) within six (6) months of the achievement of the Regulatory Approval Milestone Event meaning receiving approval from the FDA of a New Product Application for an Oragenics Product (or equivalent regulatory action in a foreign jurisdiction);

(ii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Indication Milestone Event meaning receiving approval from the FDA of a Supplemental FDA Application (or an equivalent filing with another equivalent regulatory agency) which Supplemental FDA Application sought approval of an indication for use of the Oragenics Product other than the current regulatory-approved indication; and

(iii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Product Milestone Event meaning receiving approval from the FDA of a New Product Application that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Lantibiotics Program.

Pursuant to the terms of the amendment, we will also pay Intrexon on a quarterly basis 10% of Net Sales derived in that quarter from the sale of products developed from the Lantibiotic ECC, calculated on an Oragenics Product-by-Oragenics Product basis and we will pay Intrexon on a quarterly basis 25% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

On July 21, 2016, the Lantibiotics ECC was amended to revise the definition of Field in view of a provisional patent application filing between Intrexon and Oragenics and to further clarify Oragenics' rights under the Lantibiotic ECC to genetically modified *Streptococcus mutans* that express Lantibiotic(s).

None of the Lantibiotic ECC milestones had been achieved as of September 30, 2019.

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.

In November of 2017, the Company amended the Oral Mucositis ECC to: (i) consolidate the development milestone payments into one payment of $27,500,000 being due within six months after receiving FDA approval of a New Product Application; (ii) reduce the sublicense revenue percentage from 50% to 25% of sublicensing revenue; and (iii) revise the field in which the Company has exclusive rights to its Oral Mucositis product candidate for the treatment of Oral Mucositis to clarify that the Company has an exclusive for the treatment of Oral Mucositis in humans regardless of etiology.

Pursuant to the terms of the Oral Mucositis ECC, as amended, we are obligated to pay Intrexon on a quarterly basis 12% of the net sales derived from the sale of products developed from the exclusive channel collaboration. We are also obligated to pay Intrexon on a quarterly basis, 25% of revenue obtained in that quarter from a sublicensor in the event of a sublicensing arrangement.

In November of 2017, the Stock Issuance Agreement and Oral Mucositis ECC were amended. Under the terms of the amendment, the Company has agreed to make certain payments to Intrexon upon our achievement of designated milestones in the form of shares of our 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 our financial statements with Intrexon's financial statements, or at our option make a cash payment to Intrexon. The milestone events and amounts payable are as follows:

(i) a one-time payment of twenty-seven million five hundred thousand United States dollars ($27,500,000) within six (6) months of the achievement of the Regulatory Approval Milestone Event meaning receiving approval from the FDA of a New Product Application for an Oragenics Product (or equivalent regulatory action in a foreign jurisdiction);

(ii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Indication Milestone Event meaning receiving approval from the FDA of a Supplemental FDA Application (or an equivalent filing with another equivalent regulatory agency) which Supplemental FDA Application sought approval of an indication for use of the Oragenics Product other than the current regulatory-approved indication; and

(iii) a one-time payment of five million United States dollars ($5,000,000) within six (6) months of the achievement of the New Product Milestone Event meaning receiving approval from the FDA of a New Product Application that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Program.

None of the Oral Mucositis ECC milestones had been achieved as of September 30, 2019.

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.

Leases

The Company's Alachua facility is being leased from a real estate developer for a term of five years beginning in December 2014. Under the lease agreement, the rental payments range from $9,641 per month to $10,851 per month. In June of 2019, the Company entered into an amendment for the Alachua facility for a term of five years beginning in December of 2019. Under the amended lease agreement, the rental payments range from $12,870 per month to $13,338 per month. The lease may be terminated prior to its stated expiration date upon the payment of nine-months rent.

In November of 2016, the Company entered into an amendment for the leased office space for corporate personnel located in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space is for thirty-six months commencing on March 1, 2017. Lease payments range from $4,138 per month to $4,392 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2020.

Supplemental balance sheet information related to leases is as follows:

	September 30, 2019
Operating lease right-of-use assets	$ 714,925
Operating lease liabilities - Short term	$ 135,120
Operating lease liabilities - Long term	586,170
Total operating lease liabilities	$ 721,290
Weighted Average Remaining Lease Term In Years	
Operating leases	3.97
Weighted Average Discount Rate	
Operating leases	5.67%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2019	$ 47,747
2020	163,224
2021	154,908
2022	160,056
2023	160,056
2024	146,718
Total	$ 832,709
Less: Imputed interest	(111,419)
Present value of lease liabilities	$ 721,290

The cost component of operating leases is as follows:

	For the Nine Months Ended September 30, 2019
Operating lease cost	$ 157,556
Short-term lease cost	1,719
Total lease cost	$ 159,275

Supplemental cash flow information related to operating leases is as follows:

	For the Nine Months Ended September 30, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 149,101

8. Related Party Transactions

During the three and nine months ended September 30, 2019, we paid $134,635 and $251,946, respectively; and during the three and nine months ended September 30, 2018, we paid $134,883 and $294,116, respectively, to Intrexon under the Oral Mucositis ECC and Lantibiotic ECC agreements (See Note 7). Included in accounts payable and accrued expenses at September 30, 2019 and December 31, 2018 was $55,771 and $39,607, respectively, related to unpaid invoices received from Intrexon relating to work performed under the ECC Agreements. As of September 30, 2019 and 2018 Intrexon beneficially owned approximately 3.36% and 8.3% of our outstanding common stock excluding Intrexon's ownership of our Series C Preferred which has no voting rights. In addition, during the first quarter of 2019, we paid a dividend on Series C Preferred Stock in the form of Series C Preferred Stock, to Intrexon as the sole holder of such preferred stock, pursuant to the terms of such Series C Preferred Stock (See Note 9 Shareholders' Equity—Preferred Stock).

Dr. Frederick Telling, Chairman and Director, and Dr. Alan Joslyn, Chief Executive Officer and President, participated in the Company's, March 25, 2019, underwritten public offering, (See Note 9 Shareholders' Equity—Common Stock), through the purchase of 100,000 shares and 66,667 shares, respectively, of the Company's common stock and short-term warrants to purchase 50,000 shares and 33,333 shares, and long-term warrants to purchase 50,000 shares and 33,333 shares respectively, of the Company's common stock. Dr. Telling's and Dr. Joslyn's participation in the offering was approved by the Company's Audit Committee.

9. Shareholders' Equity

Common Stock

Closing of Underwritten Public Offering

On March 25, 2019, the Company announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by the Company.

The offering was comprised of 16,666,668 shares of common stock, together with short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75. The Company granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock of the Company at the public offering price, less underwriting discounts and commissions. The underwriter did not exercise its option to purchase additional shares of common stock, however the underwriter exercised its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing.

Each short-term warrant has an exercise price of $0.75 per share of common stock, is immediately exercisable, and will expire on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following the Company's release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and will expire five years following the date of issuance.

The Company intends to use the net proceeds of the offering to fund its AG013 research, clinical trials, pre-clinical development of the lantibiotics program, and for working capital and general corporate purposes.

Other Share Issuance

On February 1, 2019, and May 1, 2019, respectively, the Company issued 12,500 shares of its common stock as partial consideration for the acquisition of certain services.

Preferred Stock

The Series A Non-Voting, Convertible 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 "Series A Preferred Stock Financing"). The full $3,000,000 of Preferred Stock, and after giving effect to the reverse stock split and the conversion of 2,583,000 shares of the Series A Preferred Stock into 258,300 shares of the Company's common stock, is convertible into nine hundred and forty one thousand seven hundred and one shares of our Common Stock, based on a fixed conversion price of $2.50 per share on an as-converted basis..

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 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 Series A Preferred Stock is classified as permanent equity.

The Series B Non-Voting, Convertible Preferred Stock Financing

On November 8, 2017, we completed a private placement of $3,300,000 of Series B Non-Voting, Convertible Preferred Stock (the "Series B Convertible Preferred Stock") pursuant to a Securities Purchase Agreement with four existing shareholders who are accredited investors including an entity affiliated with a director of the Company (the "Series B Preferred Stock Financing").

The full $3,300,000 of Series B Convertible Preferred Stock is convertible, after giving effect to the reverse stock split into one million three hundred and twenty thousand shares of our Common Stock, based on a conversion of one share of Series B Preferred Stock into two shares of Common Stock.

Except as otherwise required by law, the Series B Preferred Stock shall have no voting rights. However, as long as any shares of Series B 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 B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B 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 B Preferred Stock, (c) increase the number of authorized shares of Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

The Series B Preferred Stock shall rank (i) on par with the Common Stock and Series A Preferred Stock and junior to Series C Preferred Stock as to dividend rights and (ii) junior to Series C Preferred Stock, on par with Series A Preferred Stock and senior to the Common Stock as to distribution of assets upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive out of the assets, after payment to the holders of Series C Preferred Stock but on par with the holders of Series A Preferred Stock and in preference to the holders of the Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series B 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 B Preferred Stock if all outstanding shares of Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series B Preferred Stock is classified as permanent equity.

Series C Non-Voting, Non- Convertible Preferred Stock Financing Intrexon Debt Conversion

Each issued and outstanding share of Series C Preferred Stock entitled the holder of record, Intrexon, to receive dividends at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Preferred Stock within thirty days after the end of each calendar year pro-rata for partial years. The Initial Rate was automatically increased to twenty percent (20%) after May 10, 2019. In January of 2019 we issued 12.208 shares of the Company's Series C Preferred Stock as a dividend to Intrexon, as the holder of the Series C Preferred Stock.

Changes In Shareholders' Equity

A summary of the changes in shareholders' equity for the three and nine months ended September 30, 2019 and 2018 is as follows:

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2018	29,433,135	$ 29,433	16,017,101.733	$ 6,100,182	$ 126,125,976	$ (111,373,608)	$ 20,881,983
Compensation expense relating to option issuances	—	—	—	—	145,829	—	145,829
Issuance of common stock - shelf takedown, net of expenses	16,666,668	16,667	—	—	11,399,009	—	11,415,676
Issuance of common stock in exchange for services	12,500	12	—	—	5,988	—	6,000
Series C dividend	—	—	12.208	413,214	—	(413,214)	—
Net loss	—	—	—	—	—	(3,325,717)	(3,325,717)
Balances at March 31, 2019	46,112,303	$ 46,112	16,017,113.941	$ 6,513,396	$ 137,676,802	$ (115,112,539)	$ 29,123,771
Compensation expense relating to option issuances	—	—	—	—	164,588	—	164,588
Issuance of common stock - shelf takedown, net of expenses	—	—	—	—	(65,000)	—	(65,000)
Issuance of common stock in exchange for services	12,500	13	—	—	5,988	—	6,001
Net loss	—	—	—	—	—	(4,806,460)	(4,806,460)
Balances at June 30, 2019	46,124,803	$ 46,125	16,017,113.941	$ 6,513,396	$ 137,782,378	$ (119,918,999)	$ 24,422,900
Compensation expense relating to option issuances	—	—	—	—	232,175	—	232,175
Net loss	—	—	—	—	—	(3,836,549)	(3,836,549)
Balances at September 30, 2019	46,124,803	$ 46,125	16,017,113.941	$ 6,513,396	$ 138,014,553	$ (123,755,548)	$ 20,818,526

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2017	4,928,335	$ 4,928	18,600,100.000	$ 6,309,608	$ 101,402,570	$ (101,400,797)	$ 6,316,309
Compensation expense relating to option issuances	—	—	—	—	118,324	—	118,324
Conversion of Series A preferred stock to common stock	258,300	259	(2,583,000)	(268,096)	267,837	—	—
Series C dividend	—	—	1.733	58,670	—	(58,670)	—
Net loss	—	—	—	—	—	(2,119,397)	(2,119,397)
Balances at March 31, 2018	5,186,635	$ 5,187	16,017,101.7330	$ 6,100,182	$ 101,788,731	$ (103,578,864)	$ 4,315,236
Compensation expense relating to option issuances	—	—	—	—	81,986	—	81,986
Issuance of common stock - shelf takedown, net of expenses	900,000	900	—	—	1,509,427	—	1,510,327
Issuance of restricted common stock	16,000	16	—	—	24,304	—	24,320
Net loss	—	—	—	—	—	(2,281,289)	(2,281,289)
Balances at June 30, 2018	6,102,635	$ 6,103	16,017,101.733	$ 6,100,182	$ 103,404,448	$ (105,860,153)	$ 3,650,580
Compensation expense relating to option issuances	—	—	—	—	648,302	—	648,302
Issuance of common stock, Series D preferred stock, and warrants, net of expenses	4,436,000	4,436	9,364,000	4,464,107	7,963,085	—	12,431,628
Conversion of Series D preferred stock to common stock	7,868,000	7,868	(7,868,000)	(3,750,920)	3,743,052	—	—
Issuance of common stock in exchange for services	12,500	12	—	—	5,988	—	6,000
Net loss	—	—	—	—	—	(2,757,835)	(2,757,835)
Balances at September 30, 2018	18,419,135	$ 18,419	17,513,101.733	$ 6,813,369	$ 115,764,875	$ (108,617,988)	$ 13,978,675

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 developing 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 system 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. Approximately 770,000 patients annually in the US are at an increased risk of developing OM according to cancer statistics provided by the Center for Disease Control (CDC) in 2017. OM has a negative effect on patient well-being and if severe, negatively affects adherence to 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 also 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 ("BLA") exclusivity as well. The FDA's fast track therapy designation program is intended to facilitate the development and expedite the review of drug candidates intended for the treatment of serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs for those conditions. Under this program, FDA can, for example, review portions of a New Drug Application or BLA for a drug candidate before the entire application is complete, thus potentially beginning the review process at an earlier time.

We developed a Phase 2 protocol for AG013 with the FDA under the fast track designation. 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 we initiated the Phase 2 study with AG013 in the United States in 2017 with the expectation that we would expand the trial into Europe in 2018. The Phase 2 trial is a double-blind, placebo-controlled, 2-arm, multi-center trial in which approximately 200 patients will be randomized in a 1:1 ratio to receive either a placebo or AG013 following meals, beginning on the first day of chemoradiation therapy and continuing through the course of cancer treatment. The study is expected to enroll between 160-180 evaluable patients receiving chemoradiation for treatment of head and neck cancer for 7 to 9 weeks. The clinical trial is being conducted at clinical sites across the United States and Europe. The purpose of the Phase 2 study (NCT03234465) is to evaluate the efficacy (preventing the occurrence and shortening the duration of severe oral mucositis ("SOM"), safety and tolerability of topically administered rinse AG013 compared to placebo for reducing the incidence and severity of OM in patients undergoing traditional chemoradiation for the treatment of head and neck cancer. Key efficacy measures include collection of data regarding the duration, time to development, and overall incidence of OM (World Health Organization scale used) during the active treatment phase, beginning from the start of chemoradiation therapy until 2 weeks following its completion.

An interim safety analysis was requested by the FDA on patients from our Phase 2 clinical trial of AG013 for the treatment of OM. We completed enrollment of the interim safety analysis cohort, which included 24 randomized patients in our Phase 2 clinical trial of AG013 for the treatment OM. Nineteen of those patients were included in the unblinded safety evaluation, of which 10 received AG013. We announced positive results from our interim safety analysis in May, 2018. The study provided information that, we believe, likely indicates that the overall incidence of severe OM is less than would be anticipated in the general head and neck cancer population.

Safety was evaluated on the basis of treatment-emergent adverse events, vital signs, weight, physical examinations, clinical laboratory assessments and the presence of AG013 in whole blood. Tolerability measures (taste, consistency and smell) were collected from the patient diaries. In addition, the reasons for study treatment discontinuation were also summarized. Following review of the data by an independent Data Safety Monitoring Board (DSMB), it was concluded that the clinical trial can proceed with no changes to the study. The data analysis indicated that the distribution of adverse events was similar between AG013 and placebo. The serious adverse events reported were consistent with those commonly reported in a head and neck cancer population receiving traditional chemoradiation therapy treatments and included fevers, neutropenia, anemia, nausea and vomiting, infections and oral (mouth and throat) pain and there were no reports of AG013 related bacteremia or sepsis. Of patients that discontinued participation in the clinical study, 4 patients experienced adverse events, including 3 patients who developed nausea and vomiting, 2 patients that were non-compliant with the study procedures and 3 patients developed severe OM.

Following the clearance in May 2018, by the DSMB, we proceeded with patient enrollment for our AG013 clinical trial in the United States and we actively worked to expand the number of clinical sites, in both the United States and Europe, in order to accelerate the pace of patient enrollment. On October 15, 2018, we received clearance from the Belgian Health Authority to activate the patient enrollment process in Belgium followed by Health Authority approvals in the United Kingdom and Germany in November 2018. As a result, we incurred additional clinical trial costs, but we have significantly improved the pace of our patient enrollment. We completed our site activation activities where we have 59 clinical sites in 4 countries actively screening patients for inclusion in the clinical trial. We currently have approximately 182 patients enrolled in the trial of the contemplated 200 patients. We continue to anticipate completing the enrollment portion of the trial in the fourth quarter of 2019 with the top line results from the trial being released in early 2020.

In addition, the DSMB met in September 2019 and reviewed safety data to date on the first 100 patients who have completed the trial and determined that the clinical trial may continue with no adjustments or further review.

On September 30, 2019, we made a poster presentation at the European Society for Medical Oncology Congress where we announced initial blinded blended data from our ongoing Phase 2, placebo-controlled, clinical trial of AG013 in oral mucositis. The presentation described the methods and initial blinded results from the ongoing Phase 2 clinical trial for our lead oral mucositis product candidate, AG013. The initial blinded data, submitted in the abstract, reflected the results for 42 of the 71 enrolled and randomized patients across 48 study sites who had completed their treatment course and demonstrated that in the blinded, combined placebo and active treatment groups, there was sufficient evidence of efficacy and safety to continue the study. Additional data accumulated since poster submission, indicated the blinded efficacy evaluation, which included any patient with SOM after week one of treatment and those receiving a cumulative dose of 55 Gy (week 6 of treatment), demonstrated an overall SOM incidence of 47%, which we believe is lower than would be expected based on historical data in the head and neck cancer population receiving this chemoradiation regimen. The overall rate of SOM was reported in only 13.1 % (110 of 842) of evaluable visits. The overall safety profile continues to be consistent with those adverse events that normally occur in cancer patients receiving chemoradiation therapy. The study, however, remains blinded and individual treatment responses remain to be identified.

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, to date. 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 therapeutic agents 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. An animal 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.

Based on these early results, we selected a lead candidate, OG253, for which we had a pre-IND meeting with the FDA in November of 2015 regarding the pursuit of an IND for 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 toxins A & B and *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. We expect the IND for a first-in-human clinical study of OG716 to be filed with the FDA following our completion of the requisite studies, which we commenced in October of 2019.

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.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the United Kingdom (the "UK") electorate voted in a referendum to leave the European Union (the "EU"), which is commonly referred to as "Brexit". In March 2017, the UK government formally notified the European Council of its intention to leave the EU after it triggered Article 50 of the Lisbon Treaty to begin the two-year negotiation process establishing the terms of the exit and outlining the future relationship between the UK and the EU. Formal negotiations officially started in June 2017. After multiple votes in the British Parliament in January, March, and October 2019 failing to approve the draft Brexit withdrawal agreement with the EU, the UK government negotiated a delay to the UK's withdrawal until January 31, 2020. The new date of Brexit is still uncertain. The outcome after Brexit also continues to be uncertain, which may pose certain implications to our research, commercial and general business operations in the UK and the EU, including the approval and supply of our products. At present, it is still unclear whether and to what extent the UK will remain within or aligned to the EU system of medicines regulation, depending on the ultimate outcome of the negotiations. However, both the UK and the EU have issued detailed guidance for the industry on how medicines, medical devices and clinical trials will be separately regulated in their respective territories in the event of a 'hard Brexit', meaning an outcome where no negotiated settlement is reached.

Our preparation for Brexit, including for a potential 'hard Brexit', includes the changes necessary to meet the relevant requirements in the EU and the UK after Brexit, especially in the regulatory, research, manufacturing and supply chain areas. The principal aim is to ensure the continuity of supply to patients in Europe (EU and the UK) participating in our AG013 clinical trial.

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. We have generated limited revenues from grants and from our former consumer ProBiora3 product business through June 30, 2016 and have principally funded our operations through the sale of debt and equity securities, including the exercise of warrants issued in connection with financing transactions. 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, 2019, we had an accumulated deficit of $123,755,548 and we have yet to achieve profitability. We incurred net losses of $11,968,726 and $7,158,521for the nine months ended September 30, 2019 and September 30, 2018, respectively, and $11,326,182 and $6,731,525 for the years ended December 31, 2018 and 2017, 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. Our net revenues were $0 and $0 for the three and nine months ended September 30, 2019 and 2018, respectively, and $0 and $0, for the years ended December 31, 2018 and 2017, respectively.

Financial Overview

Research and Development Expenses

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

Our research and development expenses were $9,360,520 and $4,178,294 for the nine months ended September 30, 2019 and 2018, respectively.

Our current product development strategy contemplates an expected increase in our research and development expenses in the future as we continue the advancement of our clinical trial for our oral mucositis candidate and nonclinical product development programs for our lantibiotic product candidate. The lengthy process of completing clinical trials; seeking regulatory approval for our product candidates; and expanding the potential 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 or European Medicines Agency.

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 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 to increase for, among others, the following reasons:

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

Other Income (Expense)

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

Income Taxes

As of December 31, 2018, we have federal and state tax net operating loss carryforwards of approximately $102,984,000. Federal and state tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037. Federal tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but are subject to a limitation of 80% of federal taxable income. The state tax loss carryforwards generated subsequent to December 31, 2017, will expire through 2038, unless previously utilized. We also have federal research and development tax credit carryforwards of approximately $2,250,000. The federal tax credit carryforwards will expire through 2028, unless previously utilized.

Pursuant to Internal Revenue Service Code Sections 382 and 383, use of our net operating losses and credit carryforwards are limited due to a cumulative change in ownership of more than 50% that occurred in 2009 and in 2013. As a result of these 50% changes in ownership, the annual amount of pre-change net operating losses that may be used in periods subsequent to the change in ownership is approximately $417,000 for losses incurred through June 2009, and $3,540,000 for losses incurred through December 2013. The impact of this limitation is factored into management's valuation allowance placed against our deferred tax assets. 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, 2019 and 2018

Research and Development. Research and development expenses were $3,067,612 for the three months ended September 30, 2019 compared to $1,580,511 for the three months ended September 30, 2018, an increase of $1,487,101 or 94.1%. This increase was primarily due to increases in costs associated with work under our ECC's, including our current clinical trial for our oral mucositis product candidate, salary, insurance, and consulting of $1,478,273, $52,745, $9,208, and $5,042, respectively. This increase was partially offset by a decrease in stock-based compensation costs of $53,047.

General and Administrative. General and administrative expenses were $852,841 for the three months ended September 30, 2019 compared to $1,183,830 for the three months ended September 30, 2018, a decrease of $330,989 or 28.0%. This decrease was primarily due to decreases in costs associated stock-based compensation and filing and registration fees of $363,080 and $47,720, respectively. This decrease was partially offset by increases in costs associated with travel and entertainment, legal, insurance, employee benefits, salary, and vacation costs of $21,749, $12,583, $12,058, $12,023, $9,919, and $7,680, respectively.

Other Income. Other income, net was $83,904 for the three months ended September 30, 2019 compared to $6,506 for the three months ended September 30, 2018, resulting in an increase of $77,398. The net change was primarily attributable to an increase in interest income of $77,639.

Results of Operations for the For the Nine Months Ended September 30, 2019 and 2018

Research and Development. Research and development expenses were $9,360,520 for the nine months ended September 30, 2019 compared to $4,178,294 for the nine months ended September 30, 2018, an increase of $5,182,226 or 124.0%. This increase was primarily due to increases in costs associated with work under our ECC's, including our current clinical trial for our oral mucositis product candidate, salary, consulting, and rent and utilities of $5,083,173, $94,902, $44,625, and $14,728, respectively. This increase was partially offset by a decrease in, patents and bonus costs of $33,921 and $25,000, respectively.

General and Administrative. General and administrative expenses were $2,858,997 for the nine months ended September 30, 2019 compared to $2,991,300 for the nine months ended September 30, 2018, a decrease of $132,303 or 4.4%. This decrease was primarily due to decreases in costs associated with stock-based compensation and bonus costs of $331,332 and $163,655, respectively. This decrease was partially offset by increases in costs associated with consulting, insurance, travel and entertainment, salaries, and depreciation of $157,340, $77,309, $54,337, $49,211 and $19,587, respectively.

Other Income. Other income, net was $250,791 for the nine months ended September 30, 2019 compared to $11,073 for the nine months ended September 30, 2018, resulting in an increase of $239,718. The net change was primarily attributable to an increase in interest income of $240,428.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public offerings, and grants. During the nine months ended September 30, 2019 and September 30, 2018, our operating activities used cash of $9,076,328 and $6,101,876, 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 $20,600,120 and $20,765,707 at September 30, 2019 and December 31, 2018, respectively.

During the nine months ended September 30, 2019 and September 30, 2018, our investing activities used cash of $11,354 and $60,242, respectively.

During the nine months ended September 30, 2019 and September 30, 2018, our financing activities provided cash of $11,171,305 and $13,807,393, respectively. The cash provided by financing activities during the nine months ended September 30, 2019 and September 30, 2018 was primarily due to the proceeds from the sale of common stock, convertible preferred stock, and warrants and reductions in short term notes payable.

Financing

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

The May 2017 Series A 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 "Series A Preferred Stock Financing"). The sale of 1,200,000 shares of Series A 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 Series A Preferred Stock is convertible into 1,200,000 shares of our Common Stock. The purchase price per share of the Series A Preferred Stock is represented by $2.50 per share of the Common Stock on an as converted basis. In addition, we issued to the investors in the private placement accompanying common stock purchase warrants to purchase an aggregate of 1,064,520 shares of Common Stock (the "Series A Warrants"). The Series A Warrants have a term of seven years from the date of issuance and are non-exercisable until six (6) months after issuance and have an exercise price of $3.10 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 issuance and sale of the Series A 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 Series A 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 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 November 2017 Series B Preferred Stock Financing

On November 8, 2017, we completed a private placement of $3,300,000 of Series B, Non-Voting, Convertible Preferred Stock (the "Series B Preferred Stock") pursuant to a Securities Purchase Agreement with four existing shareholders who are accredited investors including, the Koski Family Limited Partnership, an entity affiliated with a director of the Company, (the "Series B Preferred Stock Financing").

The full $3,300,000 of Series B Preferred Stock is convertible into 1,320,000 shares of our Common Stock. The purchase price per share of the Series B Preferred Stock is represented by $2.50 per share of the Common Stock on an as converted basis. In addition, we issued to the investors in the private placement accompanying common stock purchase warrants to purchase an aggregate of 1,064,518 shares of Common Stock (the "Series B Warrants"). The Series B Warrants have a term of seven years from the date of issuance and are non-exercisable until six (6) months after issuance and have an exercise price of $3.10 per share.

The Series C Preferred Stock Issuance and Intrexon Debt Conversion

Concurrently with the Series B Preferred Stock Financing, we entered into a Debt Conversion Agreement (the "Intrexon Debt Conversion Agreement") with Intrexon pursuant to which Intrexon exchanged amounts owed by us to Intrexon under the Intrexon Note, and trade payables in the aggregate amount of approximately $3,400,000 for equity in the form of 100 shares of Series C, Non-Voting, Non-Convertible, Redeemable Preferred Stock (the "Series C Preferred Stock") issued by us to Intrexon pursuant to the Debt Conversion Agreement.

Each issued and outstanding share of Series C Preferred Stock entitles the holder of record to receive dividends at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Preferred Stock within thirty days after the end of each calendar year pro-rata for partial years. Pursuant to the terms of the Series C Preferred Stock, the Initial Rate increased to twenty percent (20%) automatically, on May 10, 2019 and such rate is applicable to periods after that date. On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Intrexon of 1.733 additional shares of Series C Preferred Stock for the portion of the 2017 fiscal year the Series C Preferred Stock was outstanding. On January 31, 2019 we paid a dividend on our Series C Preferred Stock to Intrexon of 12.208 additional shares of Series C Preferred Stock for the 2018 fiscal year the Series C Preferred Stock was outstanding.

The April 6, 2018 Registered Direct Offering and Private Placement.

On April 6, 2018, we entered into a securities purchase agreement with certain investors pursuant to which issued an aggregate of 900,000 shares of our common stock, par value $0.001 per share, at $2.00 per share. In a concurrent private placement, we issued to the investors who participated in the registered offering, warrants exercisable for one share of common stock for each share purchased in the registered offering for an aggregate of warrants to acquire 900,000 shares of common stock at an exercise price of $2.00 per share. Each warrant is exercisable beginning on the six-month anniversary of the date of its issuance and expires five years from the date of issuance.

The July 17, 2018 Underwritten Public Offering

On July 17, 2018, we closed an underwritten public offering of units for gross proceeds of approximately $13.8 million, which includes the full exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses payable by us.

The offering was comprised of Class A Units, priced at a public offering price of $1.00 per unit, with each unit consisting of one share of common stock and a seven-year warrant to purchase one share of common stock with an exercise price of $1.00 per share (each, a "Warrant" and collectively, the "Warrants"), and Class B Units, priced at a public offering price of $1.00 per unit, with each unit comprised of one share of series D preferred stock (the "Series D Preferred Stock"), which is convertible into one share of common stock, and a Warrant. The conversion price of the Series D Preferred Stock issued in the transaction as well as the exercise price of the Warrants are fixed and do not contain any variable pricing features or any price based anti-dilutive features. The Series D Preferred Stock issued in this transaction included a beneficial ownership blocker but has no dividend rights (except to the extent that dividends are also paid on the common stock), liquidation preference or other preferences over common stock, and, with certain exceptions, has no voting rights. The securities comprising the units were immediately separable and have been issued separately.

At the closing of this underwritten public offering, a total of 4,436,000 shares of common stock, 9,364,000 shares of Series D Preferred Stock convertible into 9,364,000 shares of common stock, and warrants to acquire 13,800,000 shares of common stock were issued inclusive of the underwriter's exercise of their over-allotment option to purchase 1,800,000 shares of common stock and warrants to acquire 1,800,000 shares of common stock at $1.00 per share.

Since the closing of this underwritten public offering all of the shares of Series D Preferred Stock that were issued have been converted into shares of our common stock in accordance with the terms for conversion and 9,505,500 warrants were exercised for cash generating approximately $9.5 million in proceeds to us.

The March 25, 2019 Underwritten Public Offering.

On March 25, 2019, we announced the closing of an underwritten public offering for gross proceeds of approximately $12.5 million, which included the partial exercise of the underwriter's over-allotment option to purchase additional shares and warrants, prior to deducting underwriting discounts and commissions and offering expenses. The offering is comprised of 16,666,668 shares of common stock, short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock, at a price to the public of $0.75 per share and accompanying warrants.

We granted the underwriter a 30-day option to purchase up to 2,500,000 additional shares of common stock and/or short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock the public offering price, less underwriting discounts and commissions.

The underwriter did not exercise its option to purchase additional shares of common stock, however the underwriter did exercise its option to purchase the short-term warrants to purchase 1,250,000 shares of common stock and long-term warrants to purchase 1,250,000 shares of common stock effective as of the closing. Each short-term warrant has an exercise price of $0.75 per share of common stock, is immediately exercisable, and will expire on the earlier of (1) the eighteen-month anniversary of the date of issuance and (2) twenty-one trading days following our release of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and will expire five years following the date of issuance.

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.

Products Liability Insurance

On March 10, 2019, we entered into a short-term note payable for $17,688 bearing interest at 5.69% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being due on February 10, 2020.

On March 10, 2018, we entered into a short-term note payable for $28,915 bearing interest at 5.09% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2018 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 12, 2019.

Directors' and Officers' Insurance

On August 7, 2019 we entered into a short-term note payable for $254,889 bearing interest at 5.74% 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, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being due on June 24, 2020.

On July 24, 2018, we entered into a short-term note payable for $215,575 bearing interest at 5.24% 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, 2018 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on June 27, 2019.

Future Capital Requirements

Our capital requirements for the remainder of 2019 and for 2020 will depend on numerous factors, including the progress 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 our pending clinical trials research, nonclinical testing and clinical studies, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

We believe our current available cash and cash equivalents, including the net proceeds from our recently completed public offering and warrant exercises, will allow us to fund our operating plan through the fourth quarter of 2020. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts. For example, as we continue to work with Intrexon under the Lantibiotic ECC for the development of MU1140 homologs and in our Oral Mucositis ECC including the currently pending clinical trial, we will require additional capital.

Because of the numerous risks and uncertainties associated with research, development and clinical testing 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 pace of patient enrollment in our clinical trial of AG013;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the determination to redeem all, or any portion of, our outstanding Series C Preferred Stock;
- 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 the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

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 stock-based compensation, valuation of warrants, and income tax valuation allowance. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2018. There have been no material changes to our critical accounting estimates during the three and nine months ended September 30, 2019.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three and nine months ended September 30, 2019 that have had or are expected to have a material 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, 2019 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.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 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, 2018 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, 2018 filed on March 29, 2019. 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 $12.0 million and $7.2 million for the nine months ended September 30, 2019 and September 30, 2018, respectively, and approximately $11.3 million and $6.7 million for the years ended December 31, 2018, and 2017, respectively. As of September 30, 2019, our accumulated deficit was approximately $123.8 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 significantly 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, 2019, , will be sufficient to fund our operations as presently structured through the fourth quarter of 2020. 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 and the redemption of outstanding preferred stock. 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:

- to conduct clinical trials on our AG013 product candidate;

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

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

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

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

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

Our auditor has previously 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, 2017 contained an explanatory paragraph raising substantial doubt about our ability to continue as a going concern. Our financial statements did not include any adjustments that may have been necessary in the event we were unable to continue as a going concern. Had we been unable to establish to the satisfaction of our independent registered public accounting firm that the net proceeds from our financing efforts would be sufficient to allow for the removal of this going concern qualification, we would have needed to significantly modify our operational plans for us to continue as a going concern. We believe we can continue our current level of operations with the cash we have on hand, inclusive of the net proceeds we received from our March 25, 2019 underwritten public offering, without additional financing through the fourth quarter of 2020. Absent sufficient additional financing, we may be unable to remain a going concern.

The United Kingdom's vote in favor of withdrawing from the European Union may have a negative effect on our ability to obtain marketing approval in foreign jurisdictions and could prevent our product candidates from being marketed abroad.

In order to market and sell our products in the European Union (the "EU") and many other foreign jurisdictions, we or our potential third-party collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. We or our potential third-party collaborators may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in other countries. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market.

Additionally, on June 23, 2016, the electorate in the United Kingdom (the "UK") voted in favor of leaving the EU, commonly referred to as Brexit. On March 29, 2017, the UK formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. After multiple votes in the British Parliament in January, March, and October 2019 failing to approve the draft Brexit withdrawal agreement with the EU, the UK government negotiated a delay to the UK's withdrawal until January 31, 2020. Since a significant proportion of the regulatory framework in the UK is derived from EU directives and regulations, the withdrawal could materially impact the regulatory regime with respect to the approval of our product candidate in the UK or the EU. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidate in the UK and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK and/or EU for our product candidate, which could significantly and materially harm our business.

Risks Related to Our Common Stock

The conversion of our Series A Preferred Stock, Series B Preferred Stock and the exercise of currently outstanding warrants could result in significant dilution to the holders of our common stock.

The holders of our Series A Preferred Stock and Series B Preferred Stock may convert their shares of preferred stock into shares of common stock. As of September 30, 2019, we had outstanding: (i) 9,417,000 shares of Series A Preferred Stock outstanding, which are convertible into 941,701 shares of common stock and (ii) 6,600,000 shares of Series B Preferred Stock, which are convertible into 1,320,002 shares of common stock.

In addition to our outstanding shares of preferred stock, as of September 30, 2019, there were currently outstanding warrants to purchase 26,538,593 shares of our common stock, inclusive of warrants to purchase 19,166,668 shares of common stock issued in connection our recent underwritten public offering which closed on March 25, 2019. The conversion of our Series A Preferred Stock and Series B Preferred Stock, as well as the exercise of our outstanding warrants could result in significant dilution to existing common shareholders, adversely affect the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

The Holder of Our Series C Preferred Stock (Intrexon) continues to receive dividends in additional shares of Series C Preferred Stock.

Each issued and outstanding share of Series C Preferred Stock entitled the holder of record (Intrexon) to receive dividends at the annual rate of twelve percent (12%) (the "Initial Rate") of its Stated Value, payable by issuing additional shares of Series C Preferred Stock within thirty days after the end of each calendar year. Such Initial Rate was automatically increased to a rate of twenty percent (20%), effective May 10, 2019, for periods after such date.

The issuance of additional equity securities by us in the future would result in dilution to our existing common shareholders and we recently completed an underwritten public offering which resulted in a significant increase in our outstanding shares.

Our board of directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law. Any issuance of additional equity securities by us in the future could result in dilution to our existing common shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing common shareholders. These issuances would dilute the percentage ownership interest of our existing common shareholders, which would have the effect of reducing their influence on matters on which our shareholders vote, and might dilute the book value of our common stock. For example, we issued a total of 16,666,668 shares of common stock, short-term warrants to purchase up to 8,333,334 shares of common stock, and long-term warrants to purchase up to 8,333,334 shares of common stock in our recent underwritten public offering that closed on March 25, 2019.

As a result, our outstanding shares of common stock has increased significantly from 29,433,135 shares as of December 31, 2018 to 46,124,803 shares as of September 30, 2019.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of Oragenics, Inc. Certificate of Designation and Rights of Series D Convertible Preferred Stock	8-K	001-32188	3.1	7/17/18	
3.5	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.6	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.7	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 14th day of November, 2019.

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

Exhibit 31.1

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 14th day of November, 2019

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

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

Exhibit 31.2

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 14th day of November, 2019

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

Exhibit 32.1

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 September 30, 2019 (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: November 14, 2019

Exhibit 32.2

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 September 30, 2019 (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: November 14, 2019