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 March 31, 2020.

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)

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 (check one):

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 May 15, 2020, there were 55,362,803 shares of Common Stock, $.001 par value, outstanding.

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

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Balance Sheets

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 14,372,105	$ 18,267,994
Prepaid expenses and other current assets	328,674	570,071
Total current assets	14,700,779	18,838,065
Property and equipment, net	79,654	91,968
Operating lease right-of-use assets	781,674	822,684
Total assets	$ 15,562,107	$ 19,752,717
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,786,671	$ 1,541,415
Short-term notes payable	70,847	143,864
Operating lease liabilities	167,864	165,096
Total current liabilities	2,025,382	1,850,375
Long-term liabilities:		
Operating lease liabilities	627,723	670,690
Total long-term liabilities	627,723	670,690
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, 133.483 and 113.941 Series C shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	7,174,854	6,513,396
Common stock, $0.001 par value; 200,000,000 shares authorized; 46,124,803 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	46,125	46,125
Additional paid-in capital	138,890,067	138,024,957
Accumulated deficit	(133,202,044)	(127,352,826)
Total shareholders' equity	12,909,002	17,231,652
Total liabilities and shareholders' equity	$ 15,562,107	$ 19,752,717

See accompanying notes.

Oragenics, Inc.

Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 3,712,679	$ 2,413,762
General and administrative	1,519,083	980,448
Total operating expenses	5,231,762	3,394,210
Loss from operations	(5,231,762)	(3,394,210)
Other income (expense):		
Interest income	44,515	70,090
Interest expense	(1,708)	(1,297)
Local business tax	(600)	(300)
Miscellaneous income	1,795	—
Total other income, net	44,002	68,493
Loss before income taxes	(5,187,760)	(3,325,717)
Income tax benefit	—	—
Net loss	$ (5,187,760)	$ (3,325,717)
Basic and diluted net loss per share	$ (0.11)	$ (0.11)
Shares used to compute basic and diluted net loss per share	46,124,803	30,552,302

See accompanying notes.

Oragenics, Inc.

Statements of Changes in Shareholders' Equity
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2019	46,124,803	$ 46,125	16,017,113.941	$ 6,513,396	$ 138,024,957	$ (127,352,826)	$ 17,231,652
Compensation expense relating to option issuances	—	—	—	—	865,110	—	865,110
Series C dividend	—	—	19.542	661,458	—	(661,458)	—
Net loss	—	—	—	—	—	(5,187,760)	(5,187,760)
Balances at March 31, 2020	46,124,803	$ 46,125	16,017,133.483	$ 7,174,854	$ 138,890,067	$ (133,202,044)	$ 12,909,002

	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

See accompanying notes.

Oragenics, Inc.

Statements of Cash Flows
(Unaudited)

	For the Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (5,187,760)	$ (3,325,717)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	13,125	12,870
Stock-based compensation expense	865,110	145,829
Stock issued in exchange for services	—	6,000
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	241,397	18,585
Accounts payable and accrued expenses	245,256	931,757
Net cash used in operating activities	(3,822,872)	(2,210,676)
Cash flows from financing activities:		
Payments on short-term notes payable	(73,017)	(64,376)
Net proceeds from issuance of common stock and warrants	—	11,415,676
Net cash provided by (used in) financing activities	(73,017)	11,351,300
Net increase (decrease) in cash and cash equivalents	(3,895,889)	9,140,624
Cash and cash equivalents at beginning of period	18,267,994	20,208,301
Cash and cash equivalents at end of period	$ 14,372,105	$ 29,348,925
Supplemental disclosure of cash flow information:		
Interest paid	$ 1,708	$ 1,297
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ —	$ 17,688
Stock dividend on Series C preferred stock	$ 661,458	$ 413,215
Par value of common stock issued in exchange for services	$ —	13

See accompanying notes.

Oragenics, Inc.

Notes to Financial Statements
(Unaudited)

1. Organization

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November, 1996; however, operating activity did not commence until 1999. We are focused on the creation of the TerraCoV2 immunization product candidate to combat the novel coronavirus pandemic and the further development of novel antibiotics against infectious disease and effective treatments for oral mucositis.

2. Basis of Presentation

The accompanying unaudited interim financial statements as of March 31, 2020 and December 31, 2019 (audited) and three months ended March 31, 2020 and March 31, 2019 have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") for interim financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete financial statements. In the opinion of management, the accompanying financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period ending March 31, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 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, 2019, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 4, 2020. 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 $5,187,760 and used cash of $3,822,872 in its operating activities during the three months ended March 31, 2020. As of March 31, 2020, the Company had an accumulated deficit of $133,202,044.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at March 31, 2020 will be sufficient to meet the business objectives as presently structured through the first quarter of 2021. 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

There are no accounting pronouncements issued or effective during the three months ended March 31, 2020 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 us. To the extent the stock option grants, warrants, or restricted stock grants do not vest at the grant date they are subject to forfeiture.

Stock-Based Compensation

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

Warrants

The Company used the Black Scholes Option Pricing Model in calculating the 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 March 31, 2020, the uninsured portion of this balance was $14,122,105. As of December 31, 2019, the uninsured portion of this balance was $18,017,994.

4. Stock-based Compensation

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

	For the Three Months Ended March 31, 2020	For the Three Months Ended March 31, 2019
Research and development	$ 122,519	$ 36,303
General and administrative	742,591	109,526
Total Stock-based compensation	$ 865,110	$ 145,829

The following table summarizes the stock option activity during the three months ended March 31, 2020:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value[(1)]
Outstanding at December 31, 2019	2,486,365	$ 1.47	8.67	$ 22,229
Granted	2,992,320	$ 0.48	—	$ —
Exercised	—	$ —	—	$ —
Forfeited	—	$ —	—	$ —
Outstanding at March 31, 2020	5,478,685	$ 0.93	9.21	$ 381,750
Exercisable at March 31, 2020	3,467,785	$ 1.12	9.00	$ 207,390

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as of December 31, 2019 and March 31, 2020, respectively.

Total unrecognized compensation cost related to unvested stock options was $709,978 as of March 31, 2020 and is expected to be recognized over a weighted-average period of less than one year.

As of March 31, 2020, 2,530,565 shares of common stock are available for future awards under the Plan.

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, 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. 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 had an exercise price of $0.75 per share of common stock, is immediately exercisable, and were subject to expiration 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, 2019 and the three months ended March 31, 2020 is as follows:

	Warrants	Weighted Average Price
Balance - December 31, 2018	7,371,925	$ 1.74
Granted	19,166,668	0.83
Exercised	—	—
Expired	—	—
Balance - December 31, 2019	26,538,593	1.08
Granted	—	—
Exercised	—	—
Expired	—	—
Balance - March 31, 2020	26,538,593	$ 1.08

The warrants outstanding as of March 31, 2020 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	

* As a result of the Company's release of top-line data after the end of the of the period presented, such short-term warrants expired unexercised on May 14, 2020 (except for the prior exercise of 38,000 shares). See Note 9 Subsequent Events.

All outstanding warrants are classified as equity on the Company's Balance Sheets.

6. Short-Term Notes Payable

As of March 31, 2020, and December 31, 2019, the Company had $70,847 and $143,864, 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 made on February 14, 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

The Lantibiotic ECC

Under the Company's Lantibiotic ECC with ILH Holdings, Inc. ("ILH") (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, ILH is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of ILH'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 ILH upon our achievement of designated milestones. The milestone events and amounts payable are as follows:

(i) 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 ILH 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 ILH 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 ILH 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 March 31, 2020.

The Oral Mucositis ECC

Under the Company's Exclusive Channel Collaboration Agreement with Precigen, Inc. ("Precigen) (formerly known as Intrexon Corporation) and Intrexon Actobiotics NV, a wholly-owned subsidiary of Precigen, effective January 1, 2018, Precigen assigned its interest in the license agreement to a wholly owned subsidiary, Precigen ActoBio Inc. (formerly known as ActoBio Therapeutics, Inc.)("Precigen ActoBio") (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, Precigen ActoBio 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 Precigen ActoBio 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 Precigen ActoBio 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 Precigen ActoBio 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 Precigen ActoBio to consolidate our financial statements with Precigen ActoBio's financial statements, or at our option make a cash payment to Precigen ActoBio. 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 March 31, 2020.

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 Precigen ActoBio to consolidate the Company's financial statements with Precigen ActoBio'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 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 expired on February 29, 2020. In November of 2019, the Company entered into an amendment for the Tampa facility for a term of three years beginning in March of 2020. Under the amended lease agreement, the rental payments range from $4,524 per month to $4,800 per month.

Supplemental balance sheet information related to leases is as follows:

	March 31, 2020
Operating lease right-of-use assets	$ 781,674
Operating lease liabilities - Short term	167,864
Operating lease liabilities - Long term	627,723
Total operating lease liabilities	$ 795,587
Weighted Average Remaining Lease Term In Years	
Operating leases	4.21
Weighted Average Discount Rate	
Operating leases	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2020	$ 156,549
2021	210,561
2022	217,379
2023	169,657
2024	146,718
Total	900,864
Less: Imputed interest	(105,277)
Present value of lease liabilities	$ 795,587

The cost component of operating leases is as follows:

	For the Three Months Ended March 31, 2020
Operating lease cost	55,198
Short-term lease cost	274
Total lease cost	$ 55,472

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

	For the Three Months Ended March 31, 2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 56,429

8. Shareholders' Equity

Preferred Stock

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

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. The Initial Rate was increased to twenty percent (20%) automatically after May 10, 2019.

9. Subsequent Event

On May 1, 2020, we completed our acquisition of Noachis Terra Inc., a privately-held Delaware corporation ("Noachis Terra"), dedicated to the development and commercialization of a vaccine candidate to provide specific immunity from the novel Severe Acute Respiratory Syndrome coronavirus (SARS-CoV-2), which causes the coronavirus disease 2019 ("COVID-19"), in accordance with the terms of a Stock Purchase Agreement, dated as of May 1, 2020 (the "Stock Purchase Agreement"), by and among the Company, and Mr. Joseph Hernandez, the sole shareholder of Noachis Terra. On May 1, 2020, pursuant to the Stock Purchase Agreement, the Company acquired from Mr. Hernandez one hundred percent (100%) of the issued and outstanding common stock of Noachis Terra, and Noachis Terra became a wholly-owned subsidiary of the Company (the "Transaction"). For his interest in Noachis Terra, Mr. Hernandez, received the following consideration: (i) cash consideration equal to $1,925,000, of which approximately $500,000 has been applied to extinguish Noachis Terra's pre-Transaction liabilities (a portion of which were due to Mr. Hernandez); (ii) 9,200,000 restricted shares of the Company's common stock, the sale of which shares cannot occur until the earlier of (a) the Company's share price closing above $2.50 per share, (b) the Company's announcement that it has received funding from the Biomedical Advanced Research and Development Authority ("BARDA"), or (c) six months from the Transaction's closing; and (iii) warrants to purchase 9,200,000 shares of the Company's common stock, which warrants carry an exercise price of $1.25 per share, a five-year term, and may not be exercised until the Company has obtained shareholder approval with respect to the exercisability of the warrants pursuant to the New York Stock Exchange American ("NYSE") requirements. Following such approval, the warrants may not be exercised until the earlier of (a) notification of BARDA's willingness to fund development of the TerraCoV2 vaccine product candidate, (b) phase 1 clinical results demonstrating activity, and (c) the first anniversary of the Transaction's closing.

In addition to the above consideration, Mr. Hernandez is entitled to receive contingent consideration based upon the exercise of certain of the Company's outstanding warrants as follows: (i) twenty percent (20%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $0.75 and $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding.

The Company had 9,583,334 shares attributable to short term Series 1 Warrants subject to expire on the earlier of 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. On April 15, 2020, the Company announced top-line data thereby triggering the earlier expiration of the warrants to May 14, 2020. On May 14, 2020, 9,545,334 of the Company's short-term Series 1 Warrants expired unexercised (exclusive of 38,000 shares previously exercised). As of May 15, 2020, the Company had a total of 26,155,259 warrants outstanding.

In addition, as a result of the expiration of the Company's $0.75 Series 1 Warrants, Mr. Hernandez did not receive any additional consideration associated therewith as described above.

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 as well as our Annual Report on Form 10-K for the year ended December 31, 2019 filed on March 4, 2020 and our Form 8-K filed on May 8, 2020.

As used in this quarterly report the terms "we", "us", "our", "Oragenics" and the "Company" mean Oragenics, Inc. and its wholly owned subsidiary Noachis Terra Inc., unless the context otherwise requires.

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes "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. These forward-looking statements are not historical facts, but are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. These forward-looking statements include statements about our strategies, objectives and our future achievement. To the extent statements in this Quarterly Report involve, without limitation, our expectations for growth, estimates of future revenue, our sources and uses of cash, our liquidity needs, our current or planned clinical trials or research and development activities, product development timelines, our future products, regulatory matters, expense, profits, cash flow balance sheet items or any other guidance on future periods, these statements are forward-looking statements. These statements are often, but not always, made through the use of word or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan," and "would. "These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may differ materially from those discussed in this Quarterly Report on Form 10-Q. Except as may be required by applicable law, we undertake no obligation to update any forward-looking statements or to reflect events or circumstances arising after the date of this Report. Important factors that could cause actual results to differ materially from those in these forward looking statements are in the section entitled "Risk Factors" in the most recent Annual Report on Form 10- K, as updated by our recent Form 8-K Report filed with the Securities and Exchange Commission, and the other risks and uncertainties described elsewhere in this report as well as other risks identified from time to time in our filings with the Securities and Exchange Commission, press releases and other communications. In addition, the statements contained throughout this Quarterly Report concerning future events or developments or our future activities, including concerning, among other matters, current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain sufficient funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring.

Overview

We are focused on the creation of the TerraCoV2 immunization product candidate to combat the novel coronavirus pandemic and the further development of novel antibiotics against infectious disease and effective treatments for oral mucositis.

Our SARS-CoV-2 Vaccine Product Candidate—Pre-Clinical

In May 2020, we entered into a Stock Purchase Agreement pursuant to which the Company acquired one hundred percent (100%) of the total issued and outstanding common stock of Noachis Terra, which became our wholly-owned subsidiary. We are now dedicated to the development and commercialization of a vaccine product candidate to provide specific, lifetime immunity from the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2"), which causes the coronavirus disease 2019 ("COVID-19"). We are now party to a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving prefusion coronavirus spike proteins and their use in the development and commercialization of vaccine to provide specific, lifetime immunity from SARS-CoV-2.

Coronaviruses are a family of viruses that can, when transmitted to humans, lead to upper-respiratory infections. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other bodily-system, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2 (often referred to as COVID-19), which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate of COVID-19 (as compared to the seasonal influenza). By the end of April 2020, World Health Organization estimates indicate the number of worldwide COVID-19 infections exceeded 2,500,000 and the number of deaths directly attributed to COVID-19 approached 200,000. Currently, no governmental regulatory authority has approved an immunization specifically targeting SARS-CoV-2 or COVID-19. We intend to combine the research, patent applications and biological materials covered by our NIH license with our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health crisis.

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 Precigen for the development and commercialization of the native strain of MU1140 and related homologs using Precigen's advanced transgene and cell engineering platforms. Through our work with Precigen, 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 Precigen generated a substantial number of homologs of MU1140. In January Precigen consummated a reorganization of its ongoing API fermentation operations and assets into ILH Holdings, Inc. which at the time was an affiliate of Precigen. In connection with the reorganization, Precigen assigned the Lantibiotic ECC and related stock issuance agreements to ILH Holdings. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included ILH Holdings and shares of Oragenics securities held by Precigen. As a result of such change by Precigen we expect to continue our research and development and collaboration efforts with ILH Holdings 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.

The timing of the filing of an IND regarding OG716 is subject to our having sufficient available human, material and financing capital, which includes research subjects, both animal and human, given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. We will continue to advance the OG716 program to the IND filing based on the availability of both human and financial capital. Based upon the current funding available we will continue to conduct some of the requisite studies. While we commenced certain of these studies at the end of 2019, we expect to focus on efficient and cost-effective manufacturing of the product to support and be able to conduct further broad- based studies.

Our Oral Mucositis Product Candidate-Clinical

In June of 2015, we entered into a worldwide Exclusive Channel Collaboration Agreement ("Oral Mucositis ECC") with Precigen, Inc. ("Precigen") (formerly known as Intrexon Corporation) 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.

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. In Europe, orphan status for AG013 allows us to discuss an accelerated development program with the European Medicines Agency (EMA) which may influence the duration of the program prior to marketing approval.

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 and in Europe in 2018. The Phase 2 trial was a double-blind, placebo-controlled, 2-arm, multi-center trial in which approximately 200 patients were 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 enrolled patients receiving chemoradiation for treatment of head and neck cancer for 7 to 9 weeks. The clinical trial was conducted at 60 clinical sites across the United States and Europe. The purpose of the Phase 2 study (NCT03234465) was to evaluate the efficacy (preventing the occurrence and shortening the duration of severe oral mucositis ("SOM"), safety and tolerability of topically administered AG013 rinse system compared to the 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 included collection of data regarding the duration, time to development, and overall incidence of grades 3 and 4 OM (World Health Organization scale used) during the active treatment phase, beginning from the start of chemoradiation therapy until 2 weeks following its completion.

On December 2, 2019 we announced completion of enrollment in our Phase 2 clinical trial. On April 15, 2020, we announced that early top-line results of the Phase 2 clinical trial did not demonstrate statistical significance on the primary endpoint of severe oral mucositis duration when compared to a placebo. We expect to receive and review more detailed analyses of the Phase 2 clinical trial results to determine whether AG013 may have potential efficacy for sub-patient populations.

Product Candidates.

Through our wholly-owned subsidiary, Noachis Terra, we intend to begin the research and development stage for our new TerraCoV2 vaccine product candidate. We hold a nonexclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of prefusion coronavirus spike proteins for the development and commercialization of a vaccine for SARS-CoV-2.

Additionally, we are currently developing AG013 in connection with the treatment of Oral Mucositis and a product candidate, OG716, as an antibiotic, as well as other homolog antibiotic product candidates. We have an exclusive worldwide license from Precigen and its wholly owned subsidiary, Intrexon Actobiotics NV to use their intellectual property to develop AG013 for the treatment of oral mucositis in patients undergoing treatment for cancer. Effective January 1, 2018, Precigen assigned its interest in the license agreement to a wholly owned subsidiary, Precigen ActoBio Inc. (formerly known as ActoBio Therapeutics, Inc.). We also have an exclusive, worldwide license from ILH Holdings (as an assignee of Precigen) to use its technology to develop lantibiotics. We seek to protect our product candidates through patents and patent applications pursuant to the terms of our license agreements.

Product/Candidate	Description	Application	Status
TerraCoV2	Vaccine candidate (plasmid + adjuvant) to provide lifetime immunity from SARS-CoV-2	Broad, community-based vaccine immunity and/or therapeutic	Pre-clinical
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Nonclinical testing

AG013	*Lactococcus lacti* bacterial strain genetically modified to include the gene for hTTF1	Treatment of oral mucositis in cancer patients	Enrollment completed. Awaiting full results analysis

Recent Developments

Acquisition of Noachis Terra, Inc. On May 4, 2020 we announced the acquisition of Noachis Terra Inc., to develop and commercialize TerraCoV2, a vaccine candidate which could provide specific immunity from the novel coronavirus, the root cause of coronavirus disease 2019. Noachis Terra Inc., holds a worldwide, nonexclusive license to the TerraCoV2 vaccine candidate from the National Institute of Allergy and Infectious Diseases, an institute within the National Institute of Health.

Release of Early Top-Line Results. On April 15, 2020, we announced top-line results of our Phase 2 clinical trial of AG013 in oral mucositis in chemoradiation in head and neck cancer patients and indicated that AG013 did not demonstrate statistical significance on the primary endpoint of severe oral mucositis duration when compared to placebo. AG013 was found to be safe based on review of topline adverse event information. The results are equivocal in relation to the efficacy outcomes and we now await a more detailed ongoing analyses to determine if there may be potential efficacy for sub-patient populations.

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 third parties 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 third parties. 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 $3,712,679 and $2,413,762 for the three months ended March 31, 2020 and 2019, 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.

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 our 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 vaccine 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, 2019, we have net operating loss carryforwards of approximately $117,963,000 to offset future federal and state income taxes. 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 for tax years beginning after December 21, 2020. For tax years beginning before 2021 and after December 31, 2017, the federal taxable income limitation has been removed under the CARES Act. We also have research and development tax credit carryforwards of approximately $2,805,000 as of December 31, 2019, to offset future federal and state income taxes. Our net operating loss and research and development tax credit carryforwards will expire if not used by 2039 and 2029, respectively.

Utilization of net operating loss carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or, could occur in the future in accordance with Section 382 of the Internal Revenue Code of 1986 ("IRC Section 382") and with Section 383 of the Internal Revenue Code of 1986, as well as similar state provisions. These ownership changes may limit the amount of net operating loss carryforwards and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change, as defined by IRC Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. The Company has completed several financings since its inception, as well as the recent acquisition of Noachis Terra, which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Results of Operations for the Three Months Ended March 31, 2020 and 2019

Research and Development. Research and development expenses were $3,712,679 for the three months ended March 31, 2020 compared to $2,413,762 for the three months ended March 31, 2019, an increase of $1,298,917 or 53.8%. This increase was primarily due to increases in costs associated with work under our ECC's, stock-based compensation, salaries, bonus, consulting, and insurance costs of $1,075,626, $86,216, $47,500, $36,000, $16, 200, and $11,266, respectively.

General and Administrative. General and administrative expenses were $1,519,083 for the three months ended March 31, 2020 compared to $980,448 for three months ended March 31, 2019, an increase of $538,635 or 54.9%. This increase was primarily due to increases in employee and non-employee stock-based compensation costs of $633,065. This increase was partially offset by decreases in consulting, filing fees and registrations costs, and accounting costs of $57,536, $18,891, and $13,348, respectively.

Other Income. Other income, net was $44,002 for the three months ended March 31, 2020 compared to $68,493 for the three months ended March 31, 2019, resulting in a net change of $24,491. The net change was primarily attributable to a decrease in interest income of $25,575.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public offerings, and grants. During the three months ended March 31, 2020 and March 31, 2019, our operating activities used cash of $3,822,8722, and $2,210,676, 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 $12,675,397 and $16,987,690 at March 31, 2020 and December 31, 2019, respectively.

During the three months ended March 31, 2020 and March 31, 2019, our financing activities provided or (used) cash of $(73,017) and $11,351,300, respectively. The cash provided or (used) by financing activities during the three months ended March 31, 2020 and March 31, 2019, was primarily due to the consummation of a public offering and reductions in short term notes payable.

Financing

Additional details of our financing activities for the periods reflected in this report are provided below as well as certain of our historical financings involving the issuance of preferred stock:

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 the Preferred Stock took place in two separate closings and at the first closing which occurred on May 10, 2017, we received gross proceeds of approximately $1,302,000. The second closing occurred on July 25, 2017 and we received gross proceeds of approximately $1,698,000, which was the balance of the Preferred Stock Financing. The full $3,000,000 of Preferred Stock, and after giving effect to the reverse stock split, is convertible into one million two hundred thousand shares of our Common Stock, based on a fixed conversion price of $2.50 per share on an as-converted basis. In addition, and after giving effect to the reverse stock split, we issued warrants to purchase an aggregate of 462,106 shares of Common Stock at the first closing and we issued an aggregate of 602,414 shares of Common Stock at the second closing. The warrants have a term of seven years from the date of issuance are non-exercisable until 6 months after issuance, have an exercise price of $3.10 per share. Proceeds from the Series A Preferred Stock Financing (including the exercise of any warrants for cash) will be used for general corporate purposes, including working capital.

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

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

In connection with the issuance and sale of the Series A Preferred Stock and common stock warrants that were issued commensurate with the issuance of the Series A Preferred Stock, we granted certain demand registration rights and piggyback registration rights with respect to the shares of our Common Stock issuable upon conversion of the Preferred Stock and exercise of the Warrants, pursuant to a Registration Rights Agreement.

Except as otherwise required by law, the Series A Preferred Stock shall have no voting rights. However, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that 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 May 2017 Precigen Debt Financing and ECC Amendment

On May 10, 2017, concurrently with the above referenced Series A Preferred Stock Financing, we entered into Note Purchase Agreement with Precigen pursuant to which the Company issued a $2,4000,000 unsecured non-convertible promissory note to Precigen (the "Precigen Note") and amended the first milestone in our Oral Mucositis exclusive channel collaboration agreement (the "May Oral Mucositis ECC Amendment") with Precigen. The Precigen Note matured in two (2) years and has a simple interest rate of 12% per annum. Proceeds from the Precigen Note were used to fund our AG013 research and clinical trials. In addition to, and as part of the Precigen Note, we amended the first milestone payment on the Oral Mucositis ECC from a $2,000,000 payment upon first dosing of a patient to a $3,000,000 payment upon the earlier of (a) dosing of the last patient, in a Phase 2 clinical trial, and (b) the twenty-four (24) month anniversary of the dosing of the first patient in the Phase 2 clinical trial. Simultaneously with the amendment to the Oral Mucositis ECC a similar amendment was put in place with respect to our Stock Issuance Agreement with Precigen reflecting the milestone amendment. The Precigen Note was subsequently repaid in November 2017 through the issuance of Series C Preferred Stock to Precigen (see below).

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 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. 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, and after giving effect to the reverse stock split, 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 warrants have a term of seven years from the date of issuance, and are non-exercisable until six (6) months after issuance, and after giving effect to the reverse stock split, have an exercise price of $3.10 per share.

In connection with the Series B Preferred Financing, we filed a Certificate of Designation and Rights of Series B Convertible Preferred Stock with the Secretary of State of the State of Florida, effective November 8, 2017. The number of shares of Preferred Stock designated as Series B Preferred Stock was 6,600,000.

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.

The Series C Preferred Stock Issuance and Precigen Debt Conversion

Concurrently with the Series B Preferred Stock Financing, we also entered into a Debt Conversion Agreement (the "Precigen Debt Conversion Agreement") with Precigen Corporation ("Precigen") pursuant to which Precigen exchanged the $2,400,000 unsecured non-convertible promissory note previously issued by us to Precigen (the "Precigen Note"), the accrued interest on the Precigen Note and trade payables owed by us (collectively the "Debt") in the aggregate amount of approximately $3,400,000 for equity in the form of 100 shares of Series C, Non-Voting, Non-Convertible Preferred Stock (the "Series C Preferred Stock") issued by us to Precigen pursuant to the Debt Conversion Agreement which 100 shares have a stated value equal to the amount of the Debt.

In connection with the Precigen Debt Conversion Agreement, we filed a Certificate of Designation and Rights of Series C Non-Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017. The number of shares of Preferred Stock designated as Series C Preferred Stock is 1,000.

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. The Initial Rate shall be subject to increase to twenty percent (20%) automatically after May 10, 2019.

The Series C Preferred Stock shall rank senior to the Common Stock, Series A Preferred Stock, Series B Preferred Stock and to any other equity securities issued by us (the "Junior Securities") as to rights 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 C Preferred Stock shall be entitled to receive, in preference to the Junior Securities, an amount of cash equal to the product of (i) sum of (a) the number of shares of Series C Preferred Stock then held by such holder plus, (b) the number of shares of Series C Preferred Stock issuable to such holder in connection with any accrued but unpaid dividends, multiplied by (ii) the Stated Value, of $33,847.9874 per share, of Series C Preferred Stock ("the Series C Liquidation Amount") and no distribution or payments shall be made in respect of any Junior Securities unless all Series C Liquidation Amounts, if any, are first paid in full.

On January 25, 2018 we paid a dividend on our Series C Preferred Stock to Precigen of 1.733 shares of additional Series C Preferred Stock, on January 31, 2019 we paid a dividend on our Series C Preferred Stock to Precigen of 12.208 shares of additional Series C Preferred Stock and on January 27, 2020 we paid a dividend on our Series C Preferred Stock to Precigen of 19.542 shares of additional Series C Preferred Stock. As a result of the recent sale by Precigen of its equity interest in Oragenics to TS Biotechnology LLC, future dividend payments would be paid to TS Biotechnology.

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 our 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 our 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 was 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.

In connection with the public offering, 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 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. In this public offering, 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.

On April 15, 2020, we announced top-line data on the Phase 2 clinical trial of AG013 thereby triggering the shorter expiration date of the short-term warrants to May 14, 2020. On May 14, 2020, 9,545,334 of the Company's short-term Series 1 Warrants expired unexercised (exclusive of 38,000 shares previously exercised).

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 made on February 14, 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 2020 and for 2021 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 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents provide us with limited liquidity. We believe our current available cash and cash equivalents, will allow us to fund our operating plan through the first quarter of 2021. 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 seek to move forward with the development of our TerraCoV2 vaccine candidate and our other product candidates, 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 availability of grant funding associated with the development of our TerraCoV2 vaccine product candidate;
- 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 third parties;
- 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 milestones under our 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 anticipated milestone payments, 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, 2019. There have been no material changes to our critical accounting estimates during the three months ended March 31, 2020.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three months ended March 31, 2020 that have had or are expected to have an impact on our financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Chief Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of March 31, 2020 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, 2019 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, 2019 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, 2019 filed on March 4, 2020 as updated by the Risk Factors set forth in our Form 8-K filed on May 8, 2020. 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 as updated by the Risk Factors set forth in our Form 8-K filed on May 8, 2020.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and $5.2 million and $3.3 million for the three months ended March 31, 2020 and March 31, 2019, respectively, and approximately $15.6 million and $11.3 million for the years ended December 31, 2019, and 2018, respectively. As of March 31, 2020, our accumulated deficit was approximately $133.2 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 costs associated with our plans to begin preclinical research, contract manufacturing and file an IND for our TerraCoV2 vaccine product candidate and the research and development of our product candidates pursuant to our exclusive channel partnerships with ILH Holdings, Inc. (an assignee of Precigen) in the area of lantibiotics ("Lantibiotics Program") and with Precigen's subsidiary ActoBio Therapeutics, Inc. in the area of Oral Mucositis ("Oral Mucositis Program") will continue to increase the level of our overall expenses significantly going forward. Additionally, our NIH license also requires the payment of certain recurring and performance-based royalties that may negatively impact our financial capabilities. 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. Although our application for certain Biomedical Advanced Research and Development Authority ("BARDA") funding is pending, we cannot predict our ability to obtain such funding, and you should not rely upon our obtaining such funding to finance the development of our TerraCoV2 vaccine product candidate. 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, and the progress of our efforts to develop and commercialize our product candidates, including our acquisition of a vaccine product candidate is expensive, and can cause us to use our limited, available capital resources faster than we currently anticipate. We anticipate that our cash resources as of March 31, 2020, will be sufficient to fund our operations as presently structured through the first quarter of 2021. 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. 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 or government 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 need to raise additional capital to, among other things:

- conduct preclinical research for our TerraCoV2 vaccine product candidate, file an IND with the FDA and, if approved, engage in phase 1 clinical trials;
- engage in GMP and non-GMP manufacturing for our product candidates at the preclinical research and clinical trial stages;
- expand our clinical laboratory operations;
- fund our clinical validation study activities;
- expand our research and development activities; and
- finance our capital expenditures and general and administrative expenses.

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

- the current and continued microeconomic impact of the COVID-19 pandemic on our ability, the ability of our third-party contractors and suppliers, and the ability of government regulators to conduct ordinary business operations in a timely and efficient manner, as well as the pandemic's broader, macroeconomic impact on the U.S., foreign and global economic markets;
- the level of research and development investment budgeted to develop our current and future product candidates;
- costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights;
- our need or decision to acquire or license complementary technologies or acquire complementary businesses;
- changes in test development plans needed to address any difficulties in product candidate selection for commercialization;
- competing technological and market developments;
- our interaction and relationship with the FDA, or other, regulatory agencies; and
- changes in regulatory policies or laws that affect our operations.

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

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

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

None, except as otherwise disclosed on our Form 8-K filed on May 2020.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

The information set forth below is provided in lieu of a separate Form 8-K filing pursuant to Item 5.08.

On May 15, 2020, the Board of Directors of the Company has established August 21, 2020 as the date of the Company's 2020 Annual Meeting of Shareholders (the "2020 Annual Meeting"). Because the date of the 2020 Annual Meeting has advanced by more than 30 days from the anniversary date of the Company's 2019 Annual Meeting of Stockholders (the "2019 Annual Meeting"), in accordance with Rule 14a-5(f) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), the Company is informing shareholders of such change. The record date, time and location of the 2020 Annual Meeting will be as set forth in the Company's proxy statement for the 2020 Annual Meeting.

Because the date of the 2020 Annual Meeting has been changed by more than 30 days from the anniversary of the 2019 Annual Meeting of Shareholders, a new deadline has been set for submission of proposals by Shareholders intended to be included in the Company's 2020 proxy statement and form of proxy. Proposals to be included in the Company's proxy statement for the 2020 Annual Meeting in accordance with Rule 14a-8 under the Exchange Act, must be received by the Company on or before **June 15, 2020**, which the Company believes is a reasonable time before it expects to begin to print and send its proxy materials. Shareholders must deliver the proposals or nominations to the Company's principal executive offices at the following address: Oragenics, Inc., Attn: Corporate Secretary, 4902 Eisenhower Boulevard, Suite 125, Tampa, Florida 33634.

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	
4.1	Warrant, dated May 1, 2020	8-K	001-32188	4.1	5/1/20	
10.1	Stock Purchase Agreement dated May 1, 2020	8-K	001-32188	10.1	5/1/20	
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 15th day of May, 2020.

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 15th day of May, 2020

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 15th day of May, 2020

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 March 31, 2020 (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: May 15, 2020

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 March 31, 2020 (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: May 15, 2020