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 June 30, 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 August 7, 2020, there were 61,004,917 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.

Consolidated Balance Sheets

	June 30, 2020	December 31, 2019
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 9,629,023	$ 18,267,994
Prepaid expenses and other current assets	295,490	570,071
Total current assets	9,924,513	18,838,065
Property and equipment, net	67,341	91,968
Operating lease right-of-use assets	740,086	822,684
Total assets	$ 10,731,940	$ 19,752,717
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,057,256	$ 1,541,415
Short-term notes payable	132,088	143,864
Operating lease liabilities	170,680	165,096
Total current liabilities	1,360,024	1,850,375
Long-term liabilities:		
Operating lease liabilities	583,866	670,690
Total long-term liabilities	583,866	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 June 30, 2020 and December 31, 2019, respectively	7,174,854	6,513,396
Common stock, $0.001 par value; 200,000,000 shares authorized; 55,362,803 and 46,124,803 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	55,363	46,125
Additional paid-in capital	147,097,173	138,024,957
Accumulated deficit	(145,539,340)	(127,352,826)
Total shareholders' equity	8,788,050	17,231,652
Total liabilities and shareholders' equity	$ 10,731,940	$ 19,752,717

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 11,543,973	$ 3,879,146	$ 15,256,652	$ 6,292,908
General and administrative	808,333	1,025,708	2,327,416	2,006,156
Total operating expenses	12,352,306	4,904,854	17,584,068	8,299,064
Loss from operations	(12,352,306)	(4,904,854)	(17,584,068)	(8,299,064)
Other income (expense):				
Interest income	16,495	99,427	61,010	169,517
Interest expense	(885)	(733)	(2,593)	(2,030)
Local business tax	(600)	(300)	(1,200)	(600)
Miscellaneous income	—	—	1,795	—
Total other income, net	15,010	98,394	59,012	166,887
Loss before income taxes	(12,337,296)	(4,806,460)	(17,525,056)	(8,132,177)
Income tax benefit	—	—	—	—
Net loss	$ (12,337,296)	$ (4,806,460)	$ (17,525,056)	$ (8,132,177)
Basic and diluted net loss per share	$ (0.24)	$ (0.10)	$ (0.36)	$ (0.21)
Shares used to compute basic and diluted net loss per share	52,222,473	46,120,545	49,173,638	38,330,274

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Changes in Shareholders' Equity
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
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
Compensation expense relating to option issuances	—	—	—	—	157,145	—	157,145
Issuance of common stock from warrant exercise	38,000	38	—	—	28,462	—	28,500
Issuance of common stock and warrants for the acquisition of Noachis Terra	9,200,000	9,200	—	—	8,021,499	—	8,030,699
Net loss	—	—	—	—	—	(12,337,296)	(12,337,296)
Balances at June 30, 2020	55,362,803	$ 55,363	16,017,133.483	$ 7,174,854	$ 147,097,173	$ (145,539,340)	$ 8,788,050

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

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Cash Flows
(Unaudited)

	For the Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (17,525,056)	$ (8,132,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25,985	26,192
Stock-based compensation expense	1,022,255	310,417
Stock issued in exchange for services	—	12,001
Stock issued for purchase of Noachis Terra	8,030,699	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	274,581	1,387,250
Accounts payable and accrued expenses	(484,159)	697,695
Net cash used in operating activities	(8,655,695)	(5,698,622)
Cash flows from investing activities:		
Purchase of property and equipment	—	(11,354)
Net cash used in investing activities	—	(11,354)
Cash flows from financing activities:		
Borrowings under short-term notes payable	132,088	—
Payments on short-term notes payable	(143,864)	(129,375)
Proceeds from issuance of common stock for warrant exercise	28,500	—
Net proceeds from issuance of common stock and warrants	—	11,350,676
Net cash provided by financing activities	16,724	11,221,301
Net (decrease) increase in cash and cash equivalents	(8,638,971)	5,511,325
Cash and cash equivalents at beginning of period	18,267,994	20,208,301
Cash and cash equivalents at end of period	$ 9,629,023	$ 25,719,626
Supplemental disclosure of cash flow information:		
Interest paid	$ 2,387	$ 2,045
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	$ —	25

See accompanying notes.

Oragenics, Inc.

Notes to Consolidated 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 effective treatments for novel antibiotics against infectious disease.

2. Basis of Presentation

The accompanying unaudited interim consolidated financial statements as of June 30, 2020 and December 31, 2019 (audited) and three and six months ended June 30, 2020 and 2019 have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") for interim consolidated 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 consolidated financial statements. In the opinion of management, the accompanying consolidated 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 June 30, 2020 are not necessarily indicative of the results that may be expected for the year ending December 31, 2020 or any future period.

These consolidated 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 $7,533,686 and used cash of $6,730,695 in its operating activities during the six months ended June 30, 2020. As of June 30, 2020, the Company had an accumulated deficit of $135,547,970.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at June 30, 2020, together with the proceeds from recent warrant exercises, will be sufficient to meet the business objectives as presently structured into 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

Basis of Consolidation

The consolidated financial statements include the accounts of Oragenics, Inc. and our wholly-owned subsidiary Noachis Terra, Inc. All intercompany balances and transactions have been eliminated.

Recently Issued Accounting Pronouncements

There are no additional accounting pronouncements issued or effective during the three and six months ended June 30, 2020 that have had, or are expected to have, a material impact on our consolidated financial statements.

Use of Estimates

The preparation of consolidated 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 consolidated 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 consolidated financial statements are contingent consideration, 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 consolidated 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 consolidated 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. In connection with adopting ASU 2016-09, the Company made an accounting policy election to account for forfeitures in compensation expense as they occur.

Warrants

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

Net Loss Per Share

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

Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of June 30, 2020, the uninsured portion of this balance was $9,379,023. As of December 31, 2019, the uninsured portion of this balance was $18,017,994.

4. Acquisition

On May 1, 2020, the Company entered into a Stock Purchase Agreement with the sole shareholder of Noachis Terra Inc. ("NTI"), pursuant to which the Company acquired one hundred percent (100%) of the total issued and outstanding common stock of NTI (the "Transaction"). In exchange, the shareholder received the following: (i) cash consideration equal to $1,925,000, of which approximately $500,000 has been applied to extinguish NTI's pre-Transaction liabilities (a portion of which were due to the shareholder); (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"), NIH or any other Governmental Authority to fully fund the development program for SARS-CoV-2 vaccine, 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, or (c) the first anniversary of the Transaction's closing. The Company is also obligated to pay the former sole shareholder of NTI 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.

At the closing of the Transaction, the aggregate fair value of purchase consideration was $9,955,699, consisting of $1,925,000 of cash, the Company's common stock (9,200,000 shares), and warrants to purchase the Company's common stock, as follows:

	Fair Value
Cash - Initial Cash Payment	$ 1,925,000
Equity - Common Stock	4,627,600
Equity - Warrants	3,403,099
Total fair value of consideration	$ 9,955,699

The Company determined that the acquisition should be accounted for as an asset purchase. The asset which was acquired was in-process research and development which does not have any alternative uses and therefore the aggregate fair value of the purchase price being recorded in research and development expenses in 2020.

5. Stock-based Compensation

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

	For the Three Months Ended June 30, 2020	For the Three Months Ended June 30, 2019	For the Six Months Ended June 30, 2020	For the Six Months Ended June 30, 2019
Research and development	$ 25,328	$ 35,784	$ 147,847	$ 72,087
General and administrative	131,817	128,804	874,408	238,330
Total Stock-based compensation	$ 157,145	$ 164,588	$ 1,022,255	$ 310,417

The following table summarizes the stock option activity during the six months ended June 30, 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	3,235,984	$ 0.48	—	$ —
Exercised	—	$ —	—	$ —
Forfeited	(1,000)	$ 100.00	—	$ —
Outstanding at June 30, 2020	5,721,349	$ 0.89	9.01	$ 856,600
Exercisable at June 30, 2020	3,778,519	$ 1.08	8.80	$ 473,689

(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 June 30, 2020, respectively.

Total unrecognized compensation cost related to unvested stock options was $578,529 as of June 30, 2020 and is expected to be recognized over a weighted-average period of less than two years.

As of June 30, 2020, 2,287,901 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.

6. Warrants

On May 1, 2020, the Company issued warrants to the former sole shareholder of Noachis Terra Inc. ("NTI") in connection with the Company's acquisition of NTI (the "NTI Warrants"). The NTI Warrants are exercisable at $1.25 per share, and have a five-year term. The NTI Warrants may not be exercised until the Company has obtained shareholder approval with respect to the exercisability of the NTI Warrants pursuant to the New York Stock Exchange American ("NYSE") requirements. In addition, the NTI 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, or (c) the first anniversary of the issuance of the NTI Warrants. See Note 4. Acquisition.

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.

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 expire five years following the date of issuance.

On April 15, 2020, 38,000 of the short-term warrants were exercised generating $28,500 in cash proceeds to the Company. On April 15, 2020, the Company announced the top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013. As a result, 9,545,334 of the short-term warrants expired by their terms on May 14, 2020. As of June 30, 2020, there were no short-term warrants outstanding.

A summary of warrant activity for the year ended December 31, 2019 and the three and six months ended June 30, 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	9,200,000	1.25
Exercised	(38,000)	0.75
Expired	(9,545,334)	0.75
Balance - June 30, 2020	26,155,259	$ 1.26

The warrants outstanding as of June 30, 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
$ 0.90	9,583,334	3/25/2024
$ 1.25	9,200,000	5/1/2025
	26,155,259	

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

See Note 10. Subsequent Events for information on recent exercises of certain outstanding warrants.

7. Short-Term Notes Payable

As of June 30, 2020 and December 31, 2019, the Company had $132,088 and $143,864, respectively, in short-term notes payable for the financing of various insurance policies and for the financing of certain expenses covered under the Paycheck Protection Program.

Paycheck Protection Program

On May 5, 2020, the Company received loan proceeds in the amount of $132,088 under the Paycheck Protection Program (the "PPP"). The PPP, established by the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") administered by the Small Business Administration, provides for loans to qualifying businesses for amounts up to 2.5 times the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after an initial period of eight weeks (extended to twenty-four weeks on June 5, 2020) as long as the Company uses the proceeds for eligible purposes, including payroll, benefits, rent, and utilities and maintains it payroll levels. The amount of the loan forgiveness will be reduced if the Company terminates employees or reduces salaries during the twenty-four week period.

The unforgiven portion of the PPP loan is payable over two years at an interest rate of 1%, with deferral of payments over the first six months. The Company believes that its use of the loan proceeds will meet the conditions for forgiveness of the loan, however no assurance can be provided that action will not be taken that could cause the Company to be ineligible for forgiveness of the loan, in whole or in part.

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 made on June 22, 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.

8. Commitments and Contingencies

Additional Consideration–NTI Acquisition. In connection with the Company's acquisition of NTI, the Company is obligated to pay the former sole shareholder of NTI 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.

NIH License

Through NTI, the Company is a party to a Patent License and Biological Materials License Agreement (the "License Agreement" or "NIH License"), dated March 23, 2020, with the United States Department of Health and Human Services (the "HHS"), as represented by the National Institute of Allergy and Infectious Diseases ("NIAID"), an Institute within the National Institutes of Health ("NIH"). Under the terms of the License Agreement, we hold a nonexclusive, worldwide license to certain specified patent rights (including patent applications, provisional patent applications and Patent Cooperation Treaty ("PCT") patent applications) and biological materials relating to the use of pre-fusion coronavirus spike proteins to exploit products ("Licensed Products") and practice processes ("Licensed Processes") that are covered by the licensed patent rights and biological materials for the purpose of developing and commercializing a vaccine product candidate for SARS-CoV-2.

Under the terms of the License Agreement, the NIAID is entitled to receive a non-creditable, nonrefundable upfront license issue royalty of $30,000 and reimbursement of $11,739 for our pro rata share of the NIAID's past and future patent prosecution-related expenses (which amounts have already been paid). Additionally, the NIAID is entitled to receive lump sum nonrefundable minimum annual royalties, which increase in the year after the first commercial sale of any Licensed Products or the practice of any Licensed Processes, as well as lump sum benchmark royalties following our completion of certain commercial development and sales-related benchmarks. The NIH is entitled to receive earned royalties on the annual net sales of Licensed Products and the practice of any Licensed Processes (subject to certain reductions), at certain low- to mid-single digit royalty rates, which rates vary based on the total amount of annual net sales and the geographic market in which those sales occur. We must provide regular written reports to the NIAID on the development status of and royalty payments relating to the Licensed Products and the Licensed Processes.

The License Agreement will expire upon (a) twenty (20) years from the first commercial sale where no licensed patent rights exist or have ceased to exist or (b) the expiration of the last patent contained in the licensed patent rights, unless terminated earlier. None of the applications included in the NIH licensed patent rights have issued yet. The NIH may terminate or modify the license in the event of a material breach, including if the Company does not meet certain milestones by certain dates, or upon certain insolvency events that remain uncured following the date that is 90 days following written notice of such breach or insolvency event. The Company may terminate the license, or any portion thereof, at its sole discretion at any time upon 60 days written notice to the NIH.

The Lantibiotic ECC

Under the Company's Lantibiotic ECC with ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc. ("EGI")) (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, EGI is responsible for technology discovery efforts, cell-engineering development, certain aspects of the manufacturing process, and costs of filing, prosecution and maintenance of EGI'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 EGI 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 EGI 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 EGI 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 EGI 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 June 30, 2020.

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:

	June 30, 2020
Operating lease right-of-use assets	$ 740,086
Operating lease liabilities - Short term	$ 170,680
Operating lease liabilities - Long term	583,866
Total operating lease liabilities	$ 754,546
Weighted Average Remaining Lease Term In Years	
Operating leases	3.96
Weighted Average Discount Rate	
Operating leases	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2020	$ 104,366
2021	210,561
2022	217,379
2023	169,656
2024	146,719
Total	$ 848,681
Less: Imputed interest	(94,135)
Present value of lease liabilities	$ 754,546

The cost component of operating leases is as follows:

	For the Six Months Ended June 30, 2020
Operating lease cost	$ 112,162
Short-term lease cost	738
Total lease cost	$ 112,900

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

	For the Six Months Ended June 30, 2020
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 112,846

9. Shareholders' Equity

Common Stock

On May 1, 2020, the Company issued (i) 9,200,000 shares of Common Stock and (ii) warrants to acquire 9,200,000 shares of Common Stock in connection with its acquisition of Noachis Terra Inc. See Note 4. Acquisition.

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.

10. Subsequent Events

Termination of Oral Mucositis Development Program and ECC. On July 9, 2020, the Company determined to cease further development of AG013 for the treatment of oral mucositis discontinued the Phase 2 trial and withdrew the applicable Investigational New Drug application. The Company, Precigen, Inc. ("Precigen") and Precigen's wholly owned subsidiary, also mutually agreed to terminate the Exclusive Channel Collaboration ("ECC") agreement for AG013 as a treatment of severe oral mucositis in cancer patients. The Company expects to continue to comply with any applicable regulatory requirements with respect to the discontinuation of the clinical trial.

Warrant Exercises. Between June 30, 2020 and July 28, 2020 the Company issued an additional 5,632,115 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) an additional 750,000 warrants of the Company's previously reported remaining outstanding warrants to acquire 4,294,500 shares of Common Stock at an exercise price of $1.00 per share issued in connection with its July 2018 public offering (the "2018 Warrants"), were exercised and (ii) 4,882,115 warrants of the Company's previously reported outstanding warrants to acquire 9,583,334 shares of Common Stock at an exercise price of $0.90 per share issued in connection with its March 2019 public offering (the "2019 Warrants"), were exercised (the "Warrant Exercises"). The Warrant Exercises provided aggregate gross proceeds to the Company of $5,143,903.

Additional Consideration Payment – NTI Acquisition. As a result of the Warrant Exercises, the Company paid $1,216,281 of additional consideration to the sole former shareholder of NTI. The additional consideration payment will be included in operating expenses.

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.

Our SARS-CoV-2 Vaccine Product Candidate— Terra CoV2

As a result of our acquisition of one hundred percent (100%) of the total issued and outstanding common stock of Noachis Terra Inc. ("Noachis Terra") 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"). Noachis Terra is a 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 pre-fusion 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 body-systems, 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 (as compared to the seasonal influenza). In early August 2020, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 18,000,000 and the number of deaths directly attributed to COVID-19 have exceeded 700,000. Currently, no governmental regulatory authority in the United States has approved a vaccine 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.

Corona viruses, such as SARS -CoV-2, possess signature protein spikes on their outer capsule. The NIH license covers patents and data on a vaccine candidate that was created based on a stabilized pre-fusion spike trimeric protein. By stabilizing the spike protein in ht pre-fusion state, the number of immunogenic centers is increased thereby allowing for a greater likelihood of successful antibody binding, resulting in an improved immunogenic response. The genetic code, acquired from the NIH, for the stabilized pre-fusion spike protein was provided to Aragen for the purpose of insertion of the spike protein gene sequence into a Chinese Hamster Ovary (CHO) cell line. Aragen Bioscience, a leading contract research organization focused on accelerating preclinical biologics product development, has extensive experience building CHO cell lines for recombinant proteins, such as monoclonal antibodies. Aragen has successfully inserted the NIH pre-fusion spike protein gene sequence into a CHO cell line and is currently developing both the analytical tests and identifying preliminary cell line growth conditions to optimize the spike protein titers.

While working with Aragen Bioscience, a leading contract research organization focused on accelerating preclinical biologics product development, to advance the Company's recently acquired COVID-19 vaccine candidate, TerraCoV2, the National Institutes of Health-created stabilized pre-fusion spike protein gene has been successfully inserted into Chinese Hamster Cells ("CHO") and "mini-pool" production and analytical development are underway. The transfer to full-scale manufacture is expected to commence later this summer.

The NIH's preclinical study shows that this spike protein, adjuvanted with the mouse specific TLR-4-agonist Sigma Adjuvant System (a TLR-4 agonists that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. We expect to request a Food and Drug Administration (FDA) pre-Investigational New Drug (IND) meeting in 3Q20 to refine the preclinical immunogenicity and toxicology programs, the Chemistry, Manufacturing & Controls (CMC) criteria and discuss the phase 1 clinical protocol design for the TerraCoV2 vaccine candidate. We anticipate conducting Phase 1 human clinical studies in early 2021.

We expect to use our available cash resources to continue to advance the development of TerraCoV2 with full development being contingent upon grant funding from the Biomedical Advanced Research and Development Authority ("BARDA") or the receipt of additional equity funding.

Our Antibiotic Product Candidate-OG716

Members of our scientific team discovered that a certain bacterial strain,*Streptococcus mutans,* 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 along with the increased use of currently available antibiotics due to secondary infections in SARS-CoV-2 infected patients.

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 EGI 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 EGI. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included EGI 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 EGI 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 improvements in the manufacturing process of the product as we move to complete the pre-clinical studies required to support our first in man phase 1 clinical study.

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 pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine for SARS-CoV-2.

Additionally, we are currently working with Eleszto Genetika, Inc. (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 against SARS-CoV-2	Pre-clinical
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	*Clostridium difficile* associated diarrhea	Nonclinical testing

Recent Developments

Acquisition of Noachis Terra Inc. On May 1, 2020, we entered into a Stock Purchase Agreement with the sole shareholder of Noachis Terra Inc. ("NTI"), pursuant to which we acquired one hundred percent (100%) of the total issued and outstanding common stock of NTI (the "Transaction"). In exchange, the shareholder received the following: (i) cash consideration equal to $1,925,000, of which approximately $500,000 has been applied to extinguish NTI's pre-Transaction liabilities (a portion of which were due to the shareholder); (ii) 9,200,000 restricted shares of our common stock, the sale of which shares cannot occur until the earlier of (a) our share price closing above $2.50 per share, (b) our announcement that it has received funding from the Biomedical Advanced Research and Development Authority ("BARDA"), NIH or any other Governmental Authority to fully fund the development program for SARS-CoV-2 vaccine, or (c) six months from the Transaction's closing; and (iii) warrants to purchase 9,200,000 shares of our common stock, which warrants carry an exercise price of $1.25 per share, a five-year term, and may not be exercised until we have 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, or (c) the first anniversary of the Transaction's closing. We are also obligated to pay the former sole shareholder of NTI contingent consideration based upon the exercise of certain of our outstanding warrants as follows: (i) twenty percent (20%) of the cash proceeds received by us upon exercise of our warrants carrying an exercise price of $0.75 and $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by us upon exercise of our warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding. We estimated the fair value of the contingent consideration to be $138,247 as of June 30, 2020.

Warrant Exercises. Between June 30, 2020 and July, 28, 2020 (i) 750,000 of our previously reported remaining outstanding warrants were exercised at an exercise price of $1.00 per share issued in connection with our July 2018 public offering (the "2018 Warrants") and (ii) 4,882,115 warrants of our previously reported outstanding warrants to acquire shares of Common Stock at an exercise price of $0.90 per share issued in connection with our March 2019 public offering (the "2019 Warrants"), were exercised (the "Warrant Exercises"). The Warrant Exercises provided aggregate gross proceeds to us of $5,143,903.

Additional Consideration Payment – NTI Acquisition. In connection with our acquisition of NTI we are obligated to pay additional consideration to NTI's former sole stockholder determined and based upon the exercise of our 2018 Warrants and 2019 Warrants. As a result of Warrant Exercises, we paid $1,216,281 in additional consideration to NTI's former sole stockholder.

Termination of Oral Mucositis Development Program and ECC. 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 reduction 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 were equivocal in relation to other secondary efficacy outcomes. After further analysis of the dataset, we assessed the continued pursuit of AG013 in light of such non-efficacious results, along with other factors, and based on such items, determined to no longer pursue the development of AG013 and to terminate the ECC. On July 9, 2020, the Company, Precigen, Inc. ("Precigen") and Precigen's wholly owned subsidiary mutually agreed to terminate the Exclusive Channel Collaboration ("ECC") agreement for AG013 as a treatment of severe oral mucositis in cancer patients.

Financial Overview

Impact of the Novel Coronavirus. The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, development partners, communities and business operations, as the U.S. and global economies and financial markets. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information or trends that may emerge concerning COVID-19, the actions taken to contain it or treat its impact, and the impact on local, regional, national and international markets.

Our management has closely monitored the impact of COVID-19 on our business operations. Due to stay at home orders in the United States, we have instituted a work-from-home plan for our employees. Additionally, as noted below, on May 5, 2020, the Company received loan proceeds in the amount of $132,088 under the Paycheck Protection Program (the "PPP"), pursuant to the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"). We have no plans to furlough employees at this time. However, the Company is dependent on its workforce to deliver and advance its research. While expected to be temporary, prolonged workforce disruptions may negatively impact future revenues in fiscal year 2020 and the Company's overall liquidity.

To date, we and our development partners have been able to conduct ordinary operations at or near normal levels and do not currently anticipate any interruptions for the foreseeable future. However, there could be additional repercussions for our operations, particularly for the initial development of our TerraCov2 product candidate, including but not limited to, the sourcing of materials for product candidates, manufacture of supplies for preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for trials due to such things as quarantines, conduct of patient monitoring and clinical trial data retrieval at investigational study sites. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

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 agreement with a 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 the development of our product candidates. 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 $5,265,282 and $6,292,908 for the six months ended June 30, 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 product development programs for our vaccine and lantibiotic product candidates. 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 NIH license 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, and interest earned on the stock subscription receivable. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our indebtedness.

Income Taxes

As of December 31, 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 June 30, 2020 and 2019

Research and Development. Research and development expenses were $11,543,973 for the three months ended June 30, 2020 compared to $3,879,146 for the three months ended June 30, 2019, an increase of $7,664,827 or 197.6%. This increase was primarily due to the acquisition of Noachis Terra, Inc. and an increase in costs associated with the TerraCoV2 vaccine program of $9,955,699 and $466,920, respectively. This increase was partially offset by decreases in costs associated with our clinical trial work related to our oral mucositis product candidate and under our ECC's of $2,723,807.

General and Administrative. General and administrative expenses were $808,333 for the three months ended June 30, 2020 compared to $1,025,708 for three months ended June 30, 2019, a decrease of $217,375 or 21.2%. This decrease was primarily due to decreases in filing fees and registration costs, travel and entertainment, consulting, employee stock-based compensation, and legal costs of $122,253, $39,580, $27,678, $17,869, $ 11,588, respectively.

Other Income. Other income, net was $15,010 for the three months ended June 30, 2020 compared to $98,394 for the three months ended June 30, 2019, resulting in a net change of $83,384. The net change was primarily attributable to a decrease in interest income of $82,931.

Results of Operations for the Six Months Ended June 30, 2020 and 2019

Research and Development. Research and development expenses were $15,256,652 for the six months ended June 30, 2020 compared to $6,292,908 for the six months ended June 30, 2019, an increase of $8,963,744 or 142.4% This increase was primarily due to the acquisition of Noachis Terra Inc. and an increase in costs associated with the TerraCoV2 vaccine program, employee stock-based compensation, salaries, and bonus costs of $9,955,699, $466,920, $75,760, $63,333, and $36,000, respectively. This increase was partially offset by decreases in costs associated with work under our ECC's, and in the fair value of contingent consideration of $1,648,182.

General and Administrative. General and administrative expenses were $2,327,416 for the six months ended June 30, 2020 compared to $2,006,156 for six months ended June 30, 2019, an increase of $321,260 or 16.0%. This increase was primarily due to increases in employee and non-employee stock-based compensation costs of $636,077. This increase was partially offset by decreases in filing fees and registrations costs, consulting, travel and entertainment, salaries, accounting, and legal costs of $141,142, $85,214, $40,767, $20,849, $14,020, and $13,788, respectively.

Other Income. Other income, net was $59,012 for the six months ended June 30, 2020 compared to $166,887 for the six months ended June 30, 2019, resulting in a net change of $107,875. The net change was primarily attributable to a decrease in interest income of $108,507.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public offerings, and grants. During the six months ended June 30, 2020 and June 30, 2019, our operating activities used cash of $6,730,695, and $5,698,622, 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 $8,564,489 and $16,987,690 at June 30, 2020 and December 31, 2019, respectively.

During the six months ended June 30, 2020 and June 30, 2019, our investing activities used cash of $1,925,000 and $11,354, respectively. The cash used by investing activities during the six months ended June 30, 2020 and June 30, 2019, was primarily due to the acquisition of Noachis Terra and the purchase of property and equipment.

During the six months ended June 30, 2020 and June 30, 2019, our financing activities provided cash of $16,724 and $11,221,301, respectively. The cash provided by financing activities during the six months ended June 30, 2020 and June 30, 2019, was primarily due to the consummation of a public offering and borrowing and payments 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) was 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 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 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 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

Concurrently with the Series B Preferred Stock Financing, we exchanged the amount owed on an unsecured non-convertible promissory note including accrued interest and trade payables owed by us to the noteholder (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") with a stated value equal to the amount of the Debt. In connection therewith, 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, effective November 8, 2017. The number of shares of Preferred Stock designated as Series C Preferred Stock is 1,000.

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, 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 increased to twenty percent (20%) automatically after May 10, 2019.

The Series C Preferred Stock ranks 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 of 1.733 shares of additional Series C Preferred Stock, on January 31, 2019 we paid a dividend on our Series C Preferred Stock 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 of 19.542 shares of additional Series C Preferred Stock.

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 an aggregate of 10,255,500 Warrants were exercised for cash. During October 2018, 9,505,000 shares of Company common stock were issued as a result of the voluntary exercise of such Warrants. The Warrant exercises resulted in gross proceeds to the Company of approximately $9.5 million. During July 2020 an additional 750,000 shares of Company common stock were issued as a result of the voluntary exercise of such Warrants resulted in gross proceeds to the Company of $750,000.

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.

Each short-term warrant had an exercise price of $0.75 per share of common stock, is immediately exercisable, and expired 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 our Phase 2 double blind, placebo controlled clinical trial of AG013.

As a result of our announcement of top-line data on the Phase 2 clinical trial of AG013 on April 15, 2020, the short term Warrants were subject to expiration on May 14, 2020. On May 14, 2020 9,545,334 of the Company's short-term warrants expired unexercised (exclusive of 38,000 shares previously exercised).

Each long-term warrant has an exercise price of $0.90 per share of common stock, is immediately exercisable and expires five years following the date of issuance. Through July 28, 2020 the Company issued 4,882,115 shares of Common Stock at an exercise price of $0.90 per share issued in connection with the exercise of the long-term warrants. The long-term warrant exercises provided aggregate gross proceeds to the Company of approximately $4.3 million,

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 and for the financing of certain expenses covered under the Paycheck Protection Program.

Paycheck Protection Program

On May 5, 2020, the Company received loan proceeds in the amount of $132,088 under the PPP. The PPP, established by the CARES Act and administered by the Small Business Administration, provides for loans to qualifying businesses for amounts up to 2.5 times the average monthly payroll expenses of the qualifying business. The loan and accrued interest are forgivable after an initial period of eight weeks (extended to twenty-four weeks on June 5, 2020) as long as the Company uses the proceeds for eligible purposes, including payroll, benefits, rent, and utilities and maintains it payroll levels. The amount of the loan forgiveness will be reduced if the Company terminates employees or reduces salaries during the twenty-four week period.

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 made on June 22, 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, inclusive of the proceeds from recent warrant exercises, will allow us to fund our operating plan into 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 TerraCoV2 vaccine candidate and our other product candidates, we will require additional capital. We recently applied to the BARDA requesting funding for our TerraCoV2 vaccine product candidate. In addition, we continue to pursue other COVID-19 research and development funding opportunities through governmental and nongovernmental sources, as well as potential research collaboration arrangements with academic institutions and other commercial partners. Our ability to advance the development of our TerraCoV2 vaccine candidate at our anticipated pace, in accordance with our NIH License, is dependent upon our ability to secure additional capital resources through these funding opportunities or an alternative capital raise, such as an equity or debt financing or other strategic business collaboration. Moreover, the global impact of COVID-19 could further impact our need for additional capital if we experience delays in our anticipated timelines or achievement milestones.

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, grants, 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 consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP"). The preparation of consolidated 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 consolidated 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 and six months ended June 30, 2020.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three and six months ended June 30, 2020 that have had or are expected to have an impact on our consolidated 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 June 30, 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 $7.5 million and $8.1 million for the six months ended June 30, 2020 and June 30, 2019, respectively, and approximately $15.6 million and $11.3 million for the years ended December 31, 2019, and 2018, respectively. As of June 30, 2020, our accumulated deficit was approximately $135.5 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 Eleszto Genetika, Inc. (an assignee of Precigen) in the area of lantibiotics ("Lantibiotics 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 June 30, 2020, together with the proceeds from recent warrant exercises, will be sufficient to fund our operations as presently structured into 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 4, 2020.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of Oragenics, Inc. Certificate of Designation and Rights of Series D Convertible Preferred Stock	8-K	001-32188	3.1	7/17/18	
3.5	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.6	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.7	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
4.1	Warrant dated May 1, 2020	8-K	001-32188	4.1	5/4/20	
10.1	Stock Purchase agreement dated May 1, 2020	8-K	001-32188	10.1	5/4/20	
10.2*	Non-exclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases, an institute within the National Institutes of Health					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

*Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10).

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 14th day of August, 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 10.2

[***] Portions of this exhibit have been redacted pursuant to Item 601(b)(2) of Regulation S-K as (i) not material and (ii) likely to cause competitive harm if publicly disclosed. The Company hereby undertakes to furnish unredacted copies of this exhibit upon request by the Securities and Exchange Commission; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for such unredacted copies of this exhibit.

PUBLIC HEALTH SERVICE

PATENT LICENSE-NON-EXCLUSIVE
and
BIOLOGICAL MATERIALS LICENSE-NON-EXCLUSIVE

This **Agreement** is based on the model Patent License Non-exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by

The National Institute of Allergy and Infectious Diseases

an Institute or Center (hereinafter referred to as the "**NIAID**") of the

NIH

and

Noachis Terra Inc.,

hereinafter referred to as the "**Licensee**",

having offices at 15 East Putnam Ave. Suite 363, Greenwich, CT 06830,

created and operating under the laws of Delaware.

Tax ID No.: 84-4905774

For the **IC** internal use only:

License Number: TBD

License Application Number: A-211-2020

Serial Number(s) of Licensed Patent(s) or Patent Application(s): See Appendix A.

Licensee: Noachis Terra Inc.

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

N/A

Additional Remarks:

N/A

Public Benefit(s): This license will benefite public health by allowing for development of a SARS-CoV-2 vaccine.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D ((Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options).

The **NIAID** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, the **IC** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from the **NIAID** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by the **NIAID**.

1.3 The Secretary of **HHS** has delegated to the **NIAID** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.

1.4 The **NIAID** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 [***]

2.2 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.3 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.4 [***]

2.5 [***]

2.6 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.7 "**First Commercial Sale**" means the initial transfer by or on behalf of the **Licensee** of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Licensee** in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.8 "**FDA**" means the Food and Drug Administration.

2.9 "**Government**" means the Government of the United States of America.

2.10 [***]

2.11 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.12 [***]

2.13 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.8(a):

(i) continuations-in-part of 2.8(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.8(a); and

(v) any reissues, reexaminations, and extensions of all these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.8(a): all counterpart foreign and U.S. patent applications and patents to 2.8(a) and 2.8(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.8(b) or 2.8(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.8(a).

2.14 "**Licensed Processes**" means processes, which in the course of being practiced, would be within the scope of one or more claims of the**Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.15 "**Licensed Products**" means (a) tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction or [***]

2.16 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.17 [***]

2.18 "**Net Sales**" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of the **Licensee**, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, and on its payroll, or for the cost of collections.

2.19 [***]

2.20 [***]

2.21 [***]

2.22 [***]

2.23 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.24 [***]

(a) [***];

(b) [***]; or

(c) [***].

2.25 [***]

2.26 [***]

2.27 [***]

3. GRANT OF RIGHTS

3.1 The **NIAID** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 [***]

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **IC** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 The **Licensee** has no right to sublicense.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **NIAID** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **NIAID** research use.

5.2 The **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **NIAID**.

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** agrees to pay the **NIAID** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 The **Licensee** agrees to pay the **NIAID** a minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **NIAID** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **NIAID** benchmark royalties as set forth in Appendix C.

6.5 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses; or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.6 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.7 On sales of **Licensed Products** by the **Licensee** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.8 [***]

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIAID** prior to the effective date of this **Agreement**, the **Licensee** shall pay the **NIAID**, as an additional royalty, within [***] of the **NIAID's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to [***] the unreimbursed patent expenses previously paid by the **NIAID**. [***]

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by the **NIAID** on or after the effective date of this **Agreement**, the **NIAID**, at its sole option, may require the **Licensee**:

(a) to pay the **NIAID** on an annual basis, within sixty (60) days of the **NIAID 's** submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by the **NIAID** to handle these functions. However, in this event, the **NIAID** and not the **Licensee** shall be the client of the law firm; or

(c) under exceptional circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **NIAID** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 The **NIAID** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which the **NIAID** has requested payment from the **Licensee** under Paragraphs 6.8 and 6.9. The **Licensee** agrees that all information provided by the **NIAID** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to the **NIAID** and owe no payment obligation under Paragraph 6.9 for patent-related expenses paid in that country after the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The **NIAID** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **NIAID**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the **NIAID**, by an accountant or other designated auditor selected by the **NIAID** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the **NIAID** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse the **NIAID** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the **NIAID** provides the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **NIAID** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The **NIAID** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for such differences. In any annual report, the **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by the **NIAID** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by the **NIAID** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by the **NIAID**. The **NIAID** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

9.3 The **Licensee** shall report to the **NIAID** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within [***] of such occurrences.

9.4 The **Licensee** shall submit to the **NIAID**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **IC** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.12 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **NIAID** at its address for **Agreement** Notices indicated on the Signature Page.

9.6 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

9.7 Additional royalties may be assessed by the **NIAID** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the **NIAID** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **NIAID** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.8 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **NIAID** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D.

10.2 [***]

10.3 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.4 The **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs.

10.5 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.6 The **Licensee** agrees to supply, to the Technology Transfer and Intellectual Property Office, NIAID, at the mailing address 5601 Fishers Lane, Suite 6D, Rockville, MD 20852 3804 U.S.A. for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, the **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 The **NIAID** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.

11.2 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against the **NIAID**, the **NIAID** agrees to notify the **Licensee** that an action alleging invalidity has been brought. The **NIAID** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. Upon the **Licensee's** payment of all costs incurred by the **Government** as a result of the **Licensee's** joinder motion or other action, these actions by the **Licensee** shall not be considered a default in the performance of any material obligation under this **Agreement**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **NIAID** offers no warranties other than those specified in Article 1.

12.2 The **NIAID** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 THE **NIAID** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 [***]

12.5 The **NIAID** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.6 The **Licensee** shall indemnify and hold the **NIAID**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee**, its directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by the **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.7 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.15 are not fulfilled, and shall extend [***] to the later of (a) twenty (20) years from the **First Commercial Sale** where no **Licensed Patent Rights** exist or have ceased to exist, or (b) to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **NIAID** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **NIAID** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving the **NIAID** sixty (60) days written notice to that effect.

13.5 The **NIAID** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the **NIAID** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to the **NIAID's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived.

13.6 In making the determination referenced in Paragraph 13.5, the **NIAID** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **NIAID** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **NIAID's** concerns as to the items referenced in 13.5(a)-13.5(g). If the **Licensee** fails to alleviate the **NIAID's** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the **NIAID's** satisfaction, the **NIAID** may terminate this **Agreement**.

13.7 The **NIAID** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.8 Within thirty (30) days of receipt of written notice of the **NIAID's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated the **NIAID** official. The decision of the designated **IC** official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the **NIAID** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the **NIAID** or provide the **NIAID** with written certification of the destruction thereof. The **Licensee** may not be granted additional **NIAID** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** without the prior written consent of the **NIAID**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **NIAID** approves a proposed assignment, the **Licensee** shall pay the **IC**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment

14.8 The **Licensee** agrees in its use of any **NIAID** -supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **NIAID** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **NIAID** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **NIAID** patent rights in those countries.

14.11 By entering into this **Agreement**, the **NIAID** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **NIAID**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **NIAID**, the **FDA**, **HHS**, or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **NIAID**.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **NIAID** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 8.1, 9.6-9.8, 12.1-12.5, 13.8, 13.9, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.15 The terms and conditions of this **Agreement** shall, at the **NIAID's** sole option, be considered by the **NIAID** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **NIAID** within sixty (60) days from the date of the **NIAID** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*
SIGNATURE PAGE

For the **NIAID**:

/s/ Michael R. Mowatt, PhD March 18, 2020
Micheal R. Mowatt, PhD Date
Director
Technology Transfer and Intellectual Property Office, NIAID
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the**Licensee** made or referred to in this document are truthful and accurate.):

by:
/s/ Joseph Hernandez March 18, 2020
Signature of Authorized Official Date

Joe Hernandez
Printed Name

Chairman
Title

I. Official and Mailing Address for **Agreement** notices:

Joseph Hernandez
Name

Chairman
Title

Mailing Address

15 E Putnam Avenue, Suite 363

Greenwich, CT 06830

Email Address: hernandez_joe@yahoo.com

Phone: 646-303-0737

Fax:

With copy to: **Erin Henderson, Director Corporate Relations**
Mailing Address: 3611 SW 63rd Lane, Gainesville, FL 32608
Phone: 404-405-6315
Email: erin.henderson@me.com

II. Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Joseph Hernandez
Name

Chairman
Title

Mailing Address:

15 E Putnam Avenue, Suite 363

Greenwich, CT 06830

Email Address: hernandez_joe@yahoo.com

Phone: 646-303-0737

Fax:

With copy to: **Erin Henderson, Director Corporate Relations**
Mailing Address: 3611 SW 63rd Lane, Gainesville, FL 32608
Phone: 404-405-6315
Email: erin.henderson@me.com

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

US Provisional Patent Application 62/412,703 filed 25 October 2016 entitled “Prefusion coronavirus spike proteins and their use” [HHS Ref. No. E-234-2016-0-US-01]

PCT Patent Application PCT/US2017/058370 filed 25 October 2017 entitled “Prefusion coronavirus spike proteins and their use” [HHS Ref. No. E-234-2016-1-PCT-01]

EP Patent Application 17800655.7 filed 13 May 2019, entitled “Prefusions coronavirus spike proteins and their use” [HHS Ref. No. E-234-2016-1-EP-02]

US Patent Application 16/344,774 filed 24 April 2019 entitled “Prefusion coronavirus spike proteins and their use” [HHS Ref. No. E-234-2016-1-US-03]

[***]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Products** and tangible materials**:**

(a) Plasmid expressing SARS-CoV-2 stabilized spike protein (S-2P)

(b) Plasmid expressing SARS-CoV-2 spike protein (S)

II. **Licensed Fields of Use:**

Vaccines for the prevention of infection of SARS-CoV-2 in humans

III. **Licensed Territory**:

Worldwide

IV. [***]

[***]

[***]

[***]

[***]

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **NIAID** a noncreditable, nonrefundable license issue royalty in the amount of Thirty Thousand Dollars ($30,000) within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty as follows:

(a) Thirty Thousand Dollars ($30,000) for each year prior to the **First Commercial Sale**. The first minimum annual royalty is due on [***]; and

(b) Seventy Five Thousand Dollars ($75,000) for each year after the **First Commercial Sale** due and payable within [***] of January 1 of each calendar year and shall be credited against any earned royalties due for sales made in that year.

(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay the **NIAID** earned royalties of on **Net Sales** of **[***]**:

(a) **[***]**:

(1) [***];

(2) [***];

(3) [***]

(b) **[***]**:

(1) [***];

(2) [***];

(3) [***].

IV. The **Licensee** agrees to pay the **IC Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(a) [***];

(b) [***];

(c) [***];

(d) [***].

(e) [***].

(f) [***].

APPENDIX D – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify the **IC** that the **Benchmark** has been achieved.

I. [***]

II. [***]

III. [***]

IV. [***]

V. [***]

VI. [***]

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

Noachis Terra believes a collaborative approach to development and commercialization of the 2019-nCoV vaccine will provide the most efficient and effective process to bring the vaccine to market in order to meet the current clinical need. Noachis Terra currently has active relationships with key partners to provide a seamless research, development and commercialization process. These partners will be engaged upon license approval and are poised to begin work immediately.

RESEARCH

Research activities for the vaccine will be required to determine the best use of the technology in delivering an effective vaccine for prevention and management of SARS-CoV-2 infection.

[***]

DEVELOPMENT

[***]

MARKETING

Background

The 2019-nCoV (SARS-CoV-2) virus was discovered in 2019 and has continued to spread around the globe. More than 87,000 people have proven positive for infection with almost 3,000 deaths reported. The virus is still being evaluated by global health organizations. As more data becomes available, a greater understanding of transmission and infectivity will be understood.

Currently, the highest rates of infection are located in China, South Korea, Iran and Italy, with a limited number of cases in other countries. Countries and corporations have taken unprecedented measures to ensure the safety of their citizens and employees. The U.S. government has implemented quarantine measures not seen in more than 50 years and some companies have cancelled global meetings, like Facebook. It has been reported that Japan is considering cancelling the 2020 Olympics.

The Trump Administration has requested a supplemental appropriation to fund not only preparation activities and materials, but also specifically additional funding to develop an effective vaccine for prevention of the spread of SARS-CoV-2.

Target Markets

There are two primary vaccine markets, public and private, depending on who the buyers and payers are[1]. The public market is comprised of federal or regional governmental entities. The private market is comprised consumers or individuals and private insurance payers. There are three customers roles for vaccines: consumer, buyers and payers. Consumers are the individuals receiving the vaccine. Buyers can are the people or organizations purchasing the vaccine and can be consumers, prescribers, immunization advisory groups, governments and supra-national organizations (i.e. UNICEF or Pan American Health Organization (PAHO)). Payers are those paying for the vaccine and they can include consumers, private insurance, governmental entities and non-governmental organizations like Gavi. Gavi, as an example, pays for vaccines for or its supported countries. They are projecting to financially support 54 out of 195 countries at the end of 2020.

The overall market for the vaccine is global. At present, more than 60 countries have reported cases of 2019-nCoV infection. One of the key challenges in monitoring the spread of the 2019-nCoV virus is the lack of symptoms presented by some people with the virus; cases have been reported of transmission by individuals showing no clinical manifestations, including fever, cough, shortness of breath, muscle ache, confusion, headache, sore throat, rhinorrhoea, chest pain, diarrhea, and nausea and vomiting Therefore, it is difficult to predict the total number of infections. Comprehensive vaccination of the population can reduce community transmission and lead to herd immunity therefore protecting those unable to receive the vaccine for medical reasons.

Marketing Plan

[***]

IX. MARKET ANALYSIS

Describe the relevant market segment(s) the licensed technology will serve when commercialized. Include an estimated market size (estimated patient population to be treated or diagnosed) and projected growth/reduction of relevant markets during the duration of the license. Provide an estimated market share once the product is introduced, and provide sales projections based on market share analysis.

Total Market

The total global population is approximately 7.8 billion. The population broken down by age shows 8-percent are older than 65 years of age and 26-percent are 14 years of age or younger, with 50-percent between the age of 25 and 65.2 The CDC reports that 45.3-percent of adults (18 years or greater) received the influenza vaccine in the United States and that children age 6 months to 17 years had a vaccination rate of 62.3-percent. 3 The total market for the vaccine, based upon total population and approximate estimates of vaccination rates is between 1.95 billion and 3.9 billion individuals.

Market Growth

The United Nations estimates global population growth to be approximately 81 million per year and to level off at a total global population of 10.9 million by year 2100.4 Based on the population growth predictions, the overall market will grow at approximate 1-percent per year through 2040 and then begin to slowly decrease annually to 0.1-percent.

[***]

Market Segments

Highest Risk of Developing COVID-19 – Individuals 65 and older, underlying conditions of cardiovascular disease, diabetes, hypertension, cancer and chronic respiratory disease

According to the WHO, the population most at risk of severe disease and death from the SARSCoV- 2 virus are individuals over the age of 60 and individuals with underlying conditions of cardiovascular disease, diabetes, hypertension, cancer and chronic respiratory disease. 5 The highest mortality rate reported is for people 80 years of age and older at 21.9-percent. It is estimated that onset of symptoms and severe disease is one week, while death from COVID-19 occurs between 2and 8 weeks after onset of symptoms.

[***].

Health Care Workers

The next cohort most at risk of contracting SARS-CoV-2 virus are health care workers exposed to individuals with COVID-19. Health care workers are the second highest rate of developing COVID-19 resulting in severe disease.

Adults 18-64

Severity of the disease is greater as age increases, with individuals age 50-64 years at higher risk of COVID-19 than those 49 and under.

Children 17 and under

The SARS-CoV-2 virus appears to not attack children, unlike other infectious diseases like. influenza. However, cases of asymptomatic infection have been reported in children from China, potentially . Information about the transmission of the virus is still being collected and studied to determine if children can act as asymptomatic carrier of the virus and transmit to those at higher risk of developing COVID-19. [***].

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	1,460

APPENDIX G – ROYALTY PAYMENT OPTIONS

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: **https://www.pay.gov/public/form/start/28680443.**

Automated Clearing House (ACH) for payments through U.S. banks only

The **IC** encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

Electronic Funds Wire Transfers: The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the**NIH ROYALTY FUND**.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	1000
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	021030004
{3400}	Receiver ABA short name	TREAS NYC
{3600}	Business Function Code	CTR (*or CTP*)
{4200}	Beneficiary Identifier (account number)	*(enter 12 digit gateway account #)* 875080031006
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* DHHS / NIH (75080031)
{5000}	Originator	*(enter the name of the originator of the payment)* COMPANY NAME
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* ROYALTY
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* LICENSE NUMBER
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* *INVOICE NUMBER*
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*

Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	1000
{2000}	Amount	*(enter payment amount)*
{3100}	Sender Bank ABA routing number	*(enter the US correspondent bank's ABA routing number)*
{3400}	Receiver ABA routing number*	021030004
{3400}	Receiver ABA short name	TREAS NYC
{3600}	Business Function Code	CTR (*or CTP*)
{4200}	Beneficiary Identifier (account number)**	*(enter 12 digit gateway account #)* 875080031006
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* DHHS / NIH (75080031)
{5000}	Originator	*(enter the name of the originator of the payment)* COMPANY NAME
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* ROYALTY
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* LICENSE NUMBER
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* *INVOICE NUMBER*
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*

Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045. **Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE:** FRNYUS33

Agency Contacts:

Office of Technology Transfer (OTT)	(301) 496-7057	OTT-Royalties@mail.nih.gov

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Alan Joslyn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oragenics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Dated this 14th day of August, 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 14th day of August, 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 June 30, 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: August 14, 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 June 30, 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: August 14, 2020