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

FORM 10-Q

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

For the quarterly period ended June 30, 2021.

OR

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

For the transition period from _____ to _____

Commission File Number: 001-32188

ORAGENICS, INC.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ 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 ☒ 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	☒	Smaller reporting company	☒
		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 ☒

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 15, 2021, there were 116,194,806 shares of Common Stock, $.001 par value, outstanding.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Consolidated Balance Sheets

	June 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 34,574,769	$ 17,639,575
Prepaid expenses and other current assets	86,917	343,106
Total current assets	34,661,686	17,982,681
Property and equipment, net	18,085	42,713
Operating lease right-of-use assets	567,766	655,138
Total assets	$ 35,247,537	$ 18,680,532
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,930,271	$ 937,020
Short-term notes payable	—	228,227
Operating lease liabilities	185,689	176,900
Total current liabilities	2,115,960	1,342,147
Long-term liabilities:		
Operating lease liabilities	398,177	493,790
Total long-term liabilities	398,177	493,790
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, -0- and 133.483 Series C shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	2,656,713	7,174,854
Common stock, $0.001 par value; 200,000,000 shares authorized; 116,194,806 and 91,766,928 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	116,195	91,767
Additional paid-in capital	194,558,298	164,022,957
Accumulated deficit	(164,597,806)	(154,444,983)
Total shareholders' equity	32,733,400	16,844,595
Total liabilities and shareholders' equity	$ 35,247,537	$ 18,680,532

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 2,467,575	$ 11,543,973	$ 5,728,479	$ 15,256,652
General and administrative	1,370,393	808,333	3,346,969	2,327,416
Total operating expenses	3,837,968	12,352,306	9,075,448	17,584,068
Loss from operations	(3,837,968)	(12,352,306)	(9,075,448)	(17,584,068)
Other income (expense):				
Interest income	24,254	16,495	44,287	61,010
Interest expense	(1,033)	(885)	(3,601)	(2,593)
Local business tax	(600)	(600)	(1,200)	(1,200)
Miscellaneous income	—	—	670	1,795
Total other income, net	22,621	15,010	40,156	59,012
Loss before income taxes	(3,815,347)	(12,337,296)	(9,035,292)	(17,525,056)
Income tax benefit	—	—	—	—
Net loss	$ (3,815,347)	$ (12,337,296)	$ (9,035,292)	$ (17,525,056)
Basic and diluted net loss per share	$ (0.03)	$ (0.24)	$ (0.08)	$ (0.36)
Shares used to compute basic and diluted net loss per share	115,864,162	52,222,473	109,357,191	49,173,638

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, 2020	91,766,928	$ 91,767	16,017,133.483	$ 7,174,854	$ 164,022,957	$ (154,444,983)	$ 16,844,595
Compensation expense relating to option issuances	—	—	—	—	1,123,761	—	1,123,761
Series C dividend	—	—	33.016	1,117,531	—	(1,117,531)	—
Series C redemption			(166.499)	(5,635,672)			(5,635,672)
ATM offering - net of expenses	21,398,765	21,399	—	—	26,654,993	—	26,676,392
Issuance of common stock from warrant exercise	2,472,573	2,472	—	—	2,258,864	—	2,261,336
Net loss	—	—	—	—	—	(5,219,945)	(5,219,945)
Balances at March 31, 2021	115,638,266	$ 115,638	16,017,000	$ 2,656,713	$ 194,060,575	$ (160,782,459)	$ 36,050,467
Compensation expense relating to option issuances	—	—	—	—	231,140	—	231,140
Issuance of common stock from option exercise	556,540	557	—	—	266,583	—	267,140
Net loss	—	—	—	—	—	(3,815,347)	(3,815,347)
Balances at June 30, 2021	116,194,806	116,195	16,017,000	2,656,713	194,558,298	(164,597,806)	32,733,400

	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 =	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

See accompanying notes.

Oragenics, Inc.
Consolidated Statements of Cash Flows
(Unaudited)

	For the Six Months Ended June 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (9,035,292)	$ (17,525,056)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	25,176	25,985
Stock-based compensation expense	1,354,901	1,022,255
Stock issued for purchase of Noachis Terra	—	8,030,699
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	256,189	274,581
Accounts payable and accrued expenses	993,251	(484,159)
Net cash used in operating activities	(6,405,775)	(8,655,695)
Cash flows from financing activities:		
Borrowings under short-term notes payable	—	132,088
Payments on short-term notes payable	(228,227)	(143,864)
Redemption of Series C Preferred stock	(5,635,672)	—
Proceeds from issuance of common stock for stock option exercise	267,140	—
Proceeds from issuance of common stock for warrant exercise	2,261,336	28,500
Net proceeds from issuance of common stock	26,676,392	—
Net cash provided by financing activities	23,340,969	16,724
Net increase (decrease) in cash and cash equivalents	16,935,194	(8,638,971)
Cash and cash equivalents at beginning of period	17,639,575	18,267,994
Cash and cash equivalents at end of period	$ 34,574,769	$ 9,629,023
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,601	$ 2,387
Non-cash investing and financing activities:		
Stock dividend on Series C preferred stock	$ 1,117,531	$ 661,458

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 Terra CoV-2 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, 2021 and December 31, 2020 (audited) and three and six months ended June 30, 2021 and 2020, 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 ended June 30, 2021, are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2021, 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, 2020, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2021. 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 $9,035,292 and used cash of $6,405,775 in its operating activities during the six months ended June 30, 2021. As of June 30, 2021, the Company had an accumulated deficit of $164,597,806.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at June 30, 2021 will be sufficient to meet the business objectives as presently structured into the third quarter of 2022.

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.

New Accounting Standards

There are no additional accounting pronouncements issued or effective during the three and six months ended June 30, 2021, that have had, or are expected to have, a material impact on our consolidated financial statements.

Recently Issued Accounting Pronouncements

Income Taxes

In December 2019, the FASB issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company's adoption of the provisions of ASU No. 2019-12, did not have an impact on its consolidated financial statements and related disclosures.

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 stock-based compensation, and valuation of warrants.

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, and warrants 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, 2021, the uninsured portion of this balance was $34,324,769. As of December 31, 2020, the uninsured portion of this balance was $17,389,575.

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 was 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; 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 are exercisable commencing May 1, 2021, 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, 2021	For the Three Months Ended June 30, 2020	For the Six Months Ended June 30, 2021	For the Six Months Ended June 30, 2020
Research and development	$ 48,761	$ 25,328	$ 79,688	$ 147,847
General and administrative	182,379	131,817	1,275,213	874,408
Total Stock-based compensation	$ 231,140	$ 157,145	$ 1,354,901	$ 1,022,255

The following table summarizes the stock option activity during the six months ended June 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value[(1)]
Outstanding at December 31, 2020	5,801,349	$ 0.90	8.52	$ 2,773
Granted	1,670,000	$ 1.20	—	$ —
Exercised	(556,540)	$ 0.48	—	$ —
Forfeited	(417,167)	$ 1.24	—	$ —
Outstanding at June 30, 2021	6,497,642	$ 0.99	7.26	$ 759,709
Exercisable at June 30, 2021	5,564,305	$ 1.00	6.96	$ 677,808

(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, 2020 and June 30, 2021, respectively.

Total unrecognized compensation cost related to unvested stock options was $442,856 as of June 30, 2021 and is expected to be recognized over a weighted-average period of less than two years.

As of June 30, 2021, 955,068 shares of common stock are available for future awards under the 2012 Equity Incentive Plan (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.

The Company entered into a separation agreement with its former chief executive officer which provided for severance payments as contemplated by his employment agreement and (i) accelerated the vesting of certain outstanding option awards; and (ii) extended the time for the exercise of certain vested options for one year from the date of separation. The former executive exercised options to acquire 400,000 shares of common stock during the period.

6. Warrants

During the three months ended March 31, 2021, the Company issued an additional 2,472,573 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) warrants to acquire 360,000 shares of Common Stock at an exercise price of $1.00 per share were exercised and (ii) warrants to acquire 2,112,573 shares of Common Stock at an exercise price of $0.90 per share were exercised. The warrant exercises provided aggregate gross proceeds to the Company of $2,261,336.

During the three months ended September 30, 2020, the Company issued an additional 5,642,114 shares of common stock as a result of the exercise of certain outstanding warrants as follows: (i) 760,000 shares of Common Stock at an exercise price of $1.00 per share and (ii) 4,882,114 warrants at an exercise price of $0.90 per share. The warrant exercises provided aggregate gross proceeds to the Company of $5,153,902.

On May 14, 2020 warrants to acquire 9,545,334 shares of common stock expired by their terms as a result of the Company's announcement of top-line data related to its Phase 2 double blind, placebo controlled clinical trial of AG013.

On May 1, 2020, the Company issued warrants to acquire 9,200,000 shares of Company common stock to the former sole shareholder of NTI in connection with the Company's acquisition of NTI. The NTI Warrants are exercisable at $1.25 per share commencing May 1, 2021 and have a five-year term. See Note 4. Acquisition.

A summary of warrant activity for the year ended December 31, 2020 and the six months ended June 30, 2021 is as follows:

	Warrants	Weighted Average Price
Balance - December 31, 2019	26,538,593	$ 1.08
Granted	9,200,000	1.25
Exercised	(5,680,114)	0.91
Expired	(9,545,334)	0.75
Balance - December 31, 2020	20,513,145	1.36
Granted	—	—
Exercised	(2,472,573)	0.91
Expired	—	—
Balance - June 30, 2021	18,040,572	$ 1.42

The warrants outstanding as of June 30, 2021 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	3,174,500	7/17/2025
$ 0.90	2,588,647	3/25/2024
$ 1.25	9,200,000	5/1/2025
	18,040,572	

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

7. Short-Term Notes Payable

As of June 30, 2021 and December 31, 2020, the Company had $— and $228,227, respectively, in short-term notes payable for the financing of various insurance policies.

Products Liability Insurance

On March 10, 2019, the Company entered into a short-term note payable for $17,688 bearing interest at 5.69% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 14, 2020.

Directors' and Officers' Insurance

On July 24, 2020, the Company entered into a short-term note payable for $413,784 bearing interest at 5.39% 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, 2020 and were made evenly based on a straight-line amortization over an 11-month period with the final payment being made on June 28, 2021.

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.

8. Commitments and Contingencies

Additional Consideration-NTI Acquisition. In connection with the Company's acquisition of NTI on May 1, 2020, 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 $0.90 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.

As a result of warrant exercises during the three months ended March 31, 2021, 2,472,573 warrants were exercised as follows: (i) 360,000 shares at an exercise price of $1.00 per share and (ii) 2,112,573 at an exercise price of $0.90 per share, and the Company paid $542,263 of additional consideration to the sole former shareholder of NTI and no warrants were exercised during the three-month period ended June 30, 2021. The additional consideration payment is included in research and development expenses.

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

On March 1, 2021, we entered into an amended and restated worldwide exclusive channel collaboration agreement with Eleszto Genetika, Inc. ("EGI") (the "Lantibiotic ECC") in which we will use its advanced transgene and cell engineering platforms for the development and production of lantibiotics, a class of peptide antibiotics that are naturally produced in Gram-positive bacteria and contain the characteristic polycyclic thioether amino acids lanthionine and methyllanthonine (collectively, the "Lantibiotics Program").

The Lantibiotic ECC grants us an exclusive worldwide license to use patents and other intellectual property of EGI in connection with the research, development, use, importing, exporting, manufacture, sale, and offer for sale of drug products involving the direct administration to humans or companion animals of a lantibiotic for the prevention or treatment of infectious disease ("Oragenics Products"). Such license is exclusive with respect to any clinical development, selling, offering for sale or other commercialization of Oragenics Products, and otherwise is non-exclusive. Subject to limited exceptions, we may not sublicense the rights described without Precigen's written consent.

Under the terms of the Lantibiotic ECC, we have agreed to make certain payments, in cash, to our Collaboration Partner 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 (or equivalent regulatory action in a foreign jurisdiction) for an Oragenics Product;

(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 that is deemed to be a different drug product that the first Oragenics Product that was clinically pursued under the Lantibiotics Program.

None of the Lantibiotic ECC milestones had been achieved as of June 30, 2021.

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, 2021	December 31, 2020
Weighted Average Remaining Lease Term In Years		
Operating leases	2.96	3.46
Weighted Average Discount Rate		
Operating leases	5.70%	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2021	$ 105,651
2022	217,379
2023	169,656
2024	146,719
Total	$ 639,405
Less: Imputed interest	(55,539)
Present value of lease liabilities	$ 583,866

The cost component of operating leases is as follows:

	For the Six Months Ended June 30, 2021	For The Six Months Ended June 30, 2020
Operating lease cost	$ 114,002	$ 112,162
Short-term lease cost	782	738
Total lease cost	$ 114,784	$ 112,900

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

	For the Six Months Ended June 30, 2021	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	$ 113,454	$ 112,846

9. Shareholders' Equity

Common Stock

During three months ended June 30, 2021, the Company issued 556,540 shares of common stock in connection with the exercise of stock options.

During the three months ended March 31, 2021, the Company issued an aggregate of 23,871,338 shares of common stock comprised of (i) 21,398,765 shares of common stock issued in connection with sales under its ATM Program which generated gross proceeds of approximately $27.8 million three months ended June 30, 2021 and (ii) 2,472,573 shares of common stock issued as the result of the exercise of certain outstanding warrants which generated gross proceeds of approximately $2.3 million as a result of the exercise of certain outstanding. The Company did not issue any shares pursuant to the ATM Program during the three months ended June 30, 2021.

Preferred Stock

Series C Preferred Stock Dividend and Redemption

During the three months ended March 31, 2021, the Company provided a notice of redemption, to the holder of the Company's Series C Preferred Stock to redeem all outstanding Series C Preferred Stock (which included the dividend of 26.697 shares paid on January 28, 2021 and any accrued dividends due through the redemption date of March 13, 2021). The Series C Preferred Stock redemption amount of approximately $5.6 million was paid on March 15, 2021 and all outstanding shares of Series C Preferred Stock were cancelled.

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

The following information should be read in conjunction with the Consolidated 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, 2020 filed on March 1, 2021.

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 a development stage company dedicated to fighting infectious diseases. We are focused on advancing our Terra CoV-2 vaccine candidate to combat the novel coronavirus, COVID-19, and its variants, leveraging coronavirus spike protein research licensed from the National Institutes of Health. We are also developing lantibiotics, a novel class of antibiotics, focused on combatting multidrug-resistant organisms.

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

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 focused on the development and commercialization of a vaccine product candidate to provide long lasting 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 stabilized coronavirus spike proteins and their use in the development and commercialization of a vaccine to provide specific, long lasting immunity from SARS-CoV-2.

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. 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). As of August 2021, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 203,000,000 and the number of deaths directly attributed to COVID-19 have exceeded 4,300,000. Both Pfizer and Moderna have announced preliminary safety and efficacy data from their Phase 3 COVID-19 vaccine studies and recent Emergency Use Authorization by the FDA. We believe given the size of the worldwide pandemic that even with multiple vaccines projected to be available in the coming months, there will be demand for the Terra CoV-2 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license with our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health crisis. We believe our Terra CoV-2 vaccine holds the possibility of playing an important role in addressing this crisis.

Coronaviruses, such as SARS -CoV-2, possess signature protein spikes on their outer capsule. The NIAID license covers patents and data on a vaccine candidate that were created based on a stabilized pre-fusion spike trimeric protein. By stabilizing the spike protein in the 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 Bioscience, Inc. ("Aragen") for the purpose of insertion of the spike protein gene sequence into a Chinese Hamster Ovary ("CHO") cell line. Aragen is 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. Currently, "mini-pool" production and analytical development is underway. The process to transfer to full-scale manufacture has begun.

The NIH's preclinical study shows that this spike protein, adjuvanted with the mouse specific TLR-4-agonist Sigma Adjuvant System ("SAS", 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. Recently released information indicated that pretreatment of mice with the NIH-created COVID-19 spike protein in combination with an adjuvant (TLR-4 agonist Sigma Adjuvant System) completely inhibited viral growth in the nasal cavities and lungs of infected animals compared to unvaccinated control animals. In October 2020, we received feedback to our Type B Pre-Investigational New Drug ("IND") Meeting Request from the FDA. The response indicated that the FDA broadly supported our planned approach to the pre-clinical program that will support the clinical development of the Terra CoV-2, vaccine.

We entered into an agreement with Adjuvance Technologies Inc. for the use of TQL1055, a novel, rationally designed semi-synthetic analogue of the saponin adjuvant QS-21 with potential improved attributes, including stability and manufacturing efficiency. We also anticipate that our Terra CoV-2 vaccine will provide long lasting protection from the SARS-CoV-2 virus with only one or two doses, with a more rapid immune response compared to vaccines developed without the inclusion of an adjuvant.

We also entered into a material transfer agreement with Biodextris Inc. for the use of three intranasal mucosal adjuvants in our Terra CoV-2 vaccine. BDX100, BDX300 and BDX301 are proteosome-based adjuvants comprised of proteins and lipopolysaccharides with improved attributes including enhanced immune response, manufacturing efficiency and the benefits of intranasal vaccine administration. The agreement allows for the future collaboration regarding the intranasal delivery of vaccine during clinical development with the opportunity to enter into a commercial agreement upon regulatory approval of the intranasal vaccine.

The Terra CoV-2 vaccine plus Biodextris' intranasal mucosal adjuvants will be studied in the preclinical animal studies, including hamster viral challenge studies, mouse immunogenicity studies and the rodent toxicology study required for regulatory approval prior to the initiation human testing.

We believe the Terra CoV-2 vaccine is expected to permit cost effective storage and distribution at refrigerated temperatures, which should facilitate the distribution and thereby avoid challenges facing the two mRNA vaccines currently available under the FDA's Emergency Use Authorization in the U.S.

On July 26, 2021 we entered into a licensing agreement with the National Research Council of Canada (NRC) that will enable us to pursue the rapid development of next-generation vaccines against the SARS-CoV-2 virus and its variants. The NRC technologies, in combination with the U.S. National Institutes of Health (NIH) elements found in our Terra CoV-2 vaccine, provide us with a platform that can generate cell lines for high-yield production of spike protein antigens for existing and emerging variants of concern. This platform should allow production of cell lines within six to eight weeks of spike gene sequence availability, compared with six to nine months for traditional production of such cell lines. The NRC technologies, developed with support from the NRC's Pandemic Response Challenge Program, will expedite the evaluation of SARS-CoV-2 antigen candidates in preclinical and clinical studies.

We began preclinical studies in June of 2021 through our collaboration and material transfer agreement with the NRC. We initiated an immunogenicity study in mice to evaluate several adjuvant candidates. This study is expected to be concluded in the third quarter of 2021 and we believe will allow for down-selection of the adjuvant candidates, with the best to be subsequently advanced into a hamster challenge study to assess inhibition of viral replication and an IND-enabling GLP toxicology study. As a result of the NRC License Agreement and the shift in focus to a vaccine to address evolving variants, we now expect to have another pre-IND meeting with the FDA and to file an IND application with the FDA in the first quarter of 2022 and immediately upon receipt of approval from the FDA to commence a Phase 1 clinical study, the protocol for which is currently under development.

We expect to use our currently available cash resources to continue to advance the development of Terra CoV-2 through IND-enabling studies, including immunogenicity, viral challenge studies, toxicology studies, and the Phase 1 trial with further clinical development being contingent upon the receipt of additional funding, including non-dilutive government grant funding which we continue to pursue or partnering or out-licensing opportunities.

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 antibiotic-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 a worldwide exclusive channel collaboration agreement with Precigen (formerly known as Intrexon Corporation) for the development and commercialization of the native strain of MU1140 and related homologs to use its advanced transgene and cell engineering platforms. At that time, we also entered into a stock issuance agreement with Precigen. Through our work pursuant to the collaboration agreement, 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 generated a substantial number of homologs of MU1140 and the exclusive channel collaboration was thereafter amended to clarify the applicable field and to adjust the milestone payments and provide that they will be paid in cash. In January 2020 Precigen consummated a reorganization of its ongoing active pharmaceutical ingredients (API) fermentation operations and assets which included transfer of the exclusive collaboration agreement and related stock issuance agreement. Following such reorganization, Precigen divested certain of its assets to TS Biotechnology Holdings, LLC which included shares of Oragenics securities and the subsidiary Eleszto Genetika, Inc. ("EGI" formerly known as ILH Holdings, Inc.) that held the collaboration agreement and stock issuance agreements with us, and. On March 1, 2021, due to such prior amendments, assignments and transfers we entered into an amended and restated exclusive channel collaboration agreement with EGI which (i) included the prior amendments, (ii) updated the names of the parties, and (iii) incorporated any remaining applicable terms from the stock issuance agreement and thereafter terminated the stock issuance agreement (the "Lantibiotic ECC"). We expect to continue our research and development 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 a lantibiotic product candidate 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 expect to continue to advance our lantibiotics program to an IND filing based on the availability of both human and financial capital. Based upon the current funding we expect to continue to focus on the identification of new potential product lantibiotic candidates, efficient and cost-effective improvements in the manufacturing processes and pre-clinical studies required to support a first in human Phase 1 clinical study.

Product Candidates.

Through our wholly-owned subsidiary, Noachis Terra, we began the research and development stage for our new Terra CoV-2 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 against SARS-CoV-2.

Additionally, we are developing our lead lantibiotic candidate, OG716, to treat *Clostridium difficile* while also creating semi-synthetic lantibiotic analogs that may be effective against systemic gram (+) multidrug infections, and analogs that may be effective in treating gram (-) infections. 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
Terra CoV-2	Vaccine candidate (plasmid + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
OG716	A homolog of MU1140: Member of lantibiotic class of antibiotics	*Clostridium difficile* associated diarrhea	Pre-clinical

Our Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. The large majority of product candidates do not make it past all clinical trials which forces companies to look externally for innovation. Accordingly, we expect from, time to time, to seek strategic opportunities through various forms of business development, which can include strategic alliances, licensing deals, joint ventures, collaborations, equity-or debt-based investments, dispositions, mergers and acquisitions. We view these business development activities as a necessary component of our strategies, and we seek to enhance shareholder value by evaluating business development opportunities both within and complementary to our current business as well as opportunities that may be new and separate from the development of our existing product candidates.

Recent Developments

Changes in Management and Board of Directors. On May 2, 2021, the Board appointed our Chairman of the Board, Dr. Frederick Telling to serve as Executive Chairman and appointed our Chief Financial Officer, Mr. Michael Sullivan to serve as Interim Principal Executive Officer, following the resignation of our former chief executive officer.

Addition to Our Vaccine Development Team. We recently engaged Timothy Cooke, Ph.D. as a consultant to strengthen our vaccine program. Dr. Cooke is a leading expert in domestic and global vaccine policy with more than 30 years of vaccine experience. Dr. Cooke's expertise is expected to be significantly additive to our Terra CoV-2 development roadmap and improve our ability to provide an impactful solution. Dr. Cooke currently serves as the Biotechnology Industry Representative to the U.S. National Vaccine Advisory Committee. He has also been a member of the Vaccine Policy Advisory Committee of the Biotechnology Industry Organization (BIO) and BIO's Antimicrobial Resistance Working Group. He entered the vaccine industry in 1991, joining the newly created Merck Vaccines business unit where he had domestic and international commercial responsibilities over the next nine years. He was a founding member of Sanofi Pasteur-MSD, a European joint venture for vaccine development and commercialization, and led the formation of Merck's vaccine business in Central and Eastern Europe. Dr. Cooke has had several leadership roles in the biotechnology industry, serving as Chief Executive Officer of NovaDigm Therapeutics and was previously Chief Executive Officer of Mojave Therapeutics, a company developing therapeutic vaccines against viral infections and cancer that was sold to Antigenics in 2004.

Adjournment of Annual Shareholder Meeting. On June 30, 2021, the Company adjourned its annual meeting of shareholders due to lack of a quorum to conduct the annual meeting. The meeting was adjourned to attempt to achieve a quorum and is to be reconvened on August 23, 2021 at 4:00 p.m.

Entered into License Agreement with National Research Council of Canada (NRC) On July 26, 2021, we entered into a non-exclusive Technology License Agreement (the "License Agreement") with the National Research Council of Canada ("NRC") pursuant to which the NRC grants to the Company a license to use NRC's inventions, patents, trade secrets, know-how, copyright, biological material, designs, and/or technical information created by or on behalf of the NRC (the "NRC Technologies") relating to the derivatives of CHO $^{2353\ TM}$ Cell Line listed in the License Agreement (the "Stable Cells") to: (i) make, research, and develop SARS-CoV-2 spike protein manufactured by a Stable Cell (the "Drug Substance*")* within Canada, Australia, the United Kingdom, the European Union and the United States (U.S.) (collectively the "Territory"); (ii) file regulatory approval, export and sell the final formulation of the Drug Substance ("Products") and (iii) engage contractors to use the Stable Cells to make Drug Substance or Products on behalf of the Company to be used and sold, worldwide, by the Company.

As consideration for the grant of the license, we will pay to the NRC an annual license fee, with the initial portion of the fee covering the first three years of the license. Additionally, we will pay certain milestone payments (a) upon transfer of each Stable Cell listed in the Agreement and (b) with regard to each of the first three Products, (i) upon submission of the Investigational New Drug application (IND) related thereto, (ii) upon dosing the first patient in a Phase 1 or Phase 2 clinical trial, (iii) upon dosing the first patient in a Phase 3 clinical trial and (iv) upon first regulatory approval. In addition, Oragenics will pay a low single-digit royalty to the NRC for the sale of Products, based on sales revenue, commencing after the first commercial sale.

Pursuant to the License Agreement, the NRC is required to bear the responsibility and pay the costs to obtain and maintain patents related to the NRC Technologies in the U.S., Canada, Brazil, European Union, Japan, South Korea, Singapore, Australia, China, and India, and the NRC shall use reasonable efforts to obtain and maintain those patents. Additional countries may be requested by us, in which event, the NRC will file and maintain such patents, at our expense.

Pursuant to the License Agreement, we are required to indemnify and hold the NRC and its employees and agents harmless from and against all liability and damages in connection with or arising out of all claims, demands, losses, damages, costs including solicitor and client costs, actions, suits or proceedings brought by any third party that are in any manner based upon, arising out of, related to, occasioned by, or attributable to the manufacturing, distribution, shipment, offering for sale, sale, or use of Products, services based on the NRC Technologies and product liability and infringement of intellectual property rights other than copyright, if any, licensed under the License Agreement.

Unless terminated earlier, the License Agreement will terminate twenty (20) years from the effective date of the License Agreement. Either party may terminate the License Agreement, by giving written notice to the other party, if the other party defaults or is in breach of the License Agreement, provided that if the defaulting party cures the breach within 60 days after the notice is given, the License Agreement shall continue in full force and effect. The NRC may terminate the License Agreement if the Company becomes bankrupt, or insolvent, or has a receiver appointed to continue its operations, or passes a resolution for winding up. The License Agreement contains customary confidentiality obligations.

In addition, in connection with the initiative to develop its vaccine, we also previously entered into a material transfer agreement with the NRC for SARS-CoV-2 trimeric spike protein Wuhan variant and SARS-CoV-2 trimeric spike protein South African variant to move forward with pre-clinical testing.

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. 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 operations in fiscal year 2021 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 Terra CoV-2 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, the broad emergency use authorization of vaccines, 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 license agreements with third parties and under other agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees, for and milestone payments related to, in-licensed products and technology; stock-based compensation expense; and costs associated with nonclinical activities and regulatory approvals. We expense research and development costs as incurred.

Our research and development expenses can be divided into (i) clinical research, and (ii) nonclinical research and development activities and (iii) manufacturing process development and analytical testing procedure development. 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 $5,728,479 and $15,256,652 for the six months ended June 30, 2021 and 2020, 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, with greater near-term emphasis on our vaccine product candidate. The lengthy process of completing pre-clinical studies, 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 pre-clinical studies, clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current product candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA or the regulatory authority in other jurisdictions where we may seek approval.

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, NIH license and NRC 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 development of our vaccine product candidate and 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, 2020, and 2019, we have federal and state net operating loss carryforwards of approximately $142,893,000 and $117,963,000, respectively, to offset future federal and state income taxes. Federal and state of Florida tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037. Federal and state of Florida tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire and are no longer subject to taxable income limitation pursuant to the Coronavirus Aid, Relief, and Economic Security Act, passed on March 27, 2020. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. We also have research and development tax credit carryforwards of approximately $4,043,000 and $2,805,000 as of December 31, 2020, and 2019, respectively, to offset future federal and state income taxes. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2040, unless previously utilized.

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, 2021 and 2020

Research and Development. Research and development expenses were $2,467,575 for the three months ended June 30, 2021 compared to $11,543,973 for the three months ended June 30, 2020, a decrease of $9,076,398 or 78.6%. This decrease was primarily due to prior period costs associated with the acquisition of Noachis Terra, Inc. and clinical trial work related to our oral mucositis product candidate under our ECC of $9,955,699 and $749,218, respectively. The decrease in research and development expenses was partially offset by increases in costs associated with the Terra CoV-2 vaccine program of $1,696,345 which we expect to increase in future periods.

General and Administrative. General and administrative expenses were $1,370,393 for the three months ended June 30, 2021 compared to $808,333 for three months ended June 30, 2020, an increase of $562,060 or 69.5%. This increase was primarily due to increases in filing and registration fees, salaries, employee stock-based compensation, board fees, and insurance of $207,967, $179,563, $81,341, $72,938, and $64,782. These increases were offset by decreases in costs associated with consultants, and non-employee stock-based compensation costs of $38,626, and $30,778, respectively.

Other Income. Other income, net was $22,621 for the three months ended June 30, 2021 compared to $15,010 for the three months ended June 30, 2020, resulting in an increase of $7,611. The net change was primarily attributable to an increase in interest income of $7,759.

Results of Operations for the Six Months Ended June 30, 2021 and 2020

Research and Development. Research and development expenses were $5,728,479 for the six months ended June 30, 2021 compared to $15,256,652 for the six months ended June 30, 2020, a decrease of $9,528,173 or 62.5%. This decrease was primarily due to decreases in costs associated with the acquisition of Noachis Terra, Inc., clinical trial work related to our oral mucositis product candidate under our ECC, costs associated with our lantibiotic ECC and employee stock-based compensation, of $9,955,699, $3,895,667, and $170,497, and $68,159, respectively. These decreases were partially offset by increases in costs associated with the Terra CoV-2 vaccine program and consideration relating to the acquisition of Noachis Terra, Inc., of $4,123,915 and $542,263, respectively.

General and Administrative. General and administrative expenses were $3,346,969 for the six months ended June 30, 2021 compared to $2,327,416 for six months ended June 30, 2020, an increase of $1,019,553 or 43.8%. This increase was primarily due to increases in non-employee stock-based compensation, filing and registration fees, salaries, insurance, and board fees of $589,461, $235,928, $179,178, $125,126, and $114,208. These increases were offset by a decrease in costs associated with employee stock-based compensation costs of $188,655.

Other Income. Other income, net was $40,156 for the six months ended June 30, 2021 compared to $59,012 for the six months ended June 30, 2020, resulting in a net change of $18,856. The net change was primarily attributable to a decrease in interest income of $16,273.

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, 2021 and June 30, 2020 our operating activities used cash of $6,405,775, and $8,655,695, 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 $32,545,726 and $16,640,534 at June 30, 2021 and December 31, 2020, respectively.

During the six months ended June 30, 2021 and June 30, 2020, our financing activities provided and used cash of $23,340,969 and $16,724 respectively. The cash provided by and used in financing activities during the six months ended June 30, 2021 and June 30, 2020, was primarily due to the sales of common stock, the exercise of warrants, the redemption of the Series C Preferred stock and payments on 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 information on our outstanding shares of preferred stock:

November 2020 Public Offering.

On November 24, 2020, we closed an underwritten public offering for gross proceeds of approximately $6.0 million, which included the full exercise of the underwriter's over-allotment option to purchase additional shares, prior to deducting underwriting discounts and commissions and offering expenses. The offering was comprised of 14,189,189 shares of common stock at a price to the public of $0.37 per share. We granted the underwriter a 45-day option to purchase up to 2,128,378 additional shares of our common stock at the public offering price, less underwriting discounts and commissions. The underwriter exercised its option in full to purchase 2,128,378 additional shares of common stock, which the indicated gross proceeds reflect. We intend to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital. Dr. Frederick Telling who is a Director of the Company, participated in the offering through the purchase of 100,000 shares of the Company's common stock. Dr. Telling's participation was approved by the Company's Audit Committee.

December 2020 Registered Direct Offering.

On December 29, 2020, we closed a registered direct offering for gross proceeds of approximately $6.5 million, prior to deducting underwriting discounts and commissions and offering expenses. The offering was comprised of 14,444,444 shares of common stock at a price to the public of $0.45 per share. We intend to use the net proceeds of the offering primarily to continue funding our pre-clinical development of our SARS-CoV-2 vaccine, Terra CoV-2 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

ATM Program

On February 1, 2021, we entered into a Sales Agreement (the "Sales Agreement") with A.G.P./Alliance Global Partners, as sales agent (the "Sales Agent"), pursuant to which we may offer and sell through or to the Sales Agent shares of our Common Stock (the "ATM Program"). During the three months ended March 31, 2021, we issued an aggregate of 21,398,765 shares of Common Stock and received gross proceeds of an aggregate of approximately $27.8 million under our ATM Program. We did not issue any shares under our ATM Program during the three months ended June 30, 2021. Any Shares offered and sold in the ATM Program were issued pursuant to our universal shelf registration statement on Form S-3 (the "Shelf Registration Statement"). The ATM Program will terminate upon (a) the election of the Agent upon the occurrence of certain adverse events, (b) 10 days' advance notice from one party to the other, or (c) the sale of the balance available under our Shelf Registration Statement. Under the terms of the Sales Agreement, the Sales Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sales Agreement.

Other Financings

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

Products Liability Insurance

On March 10, 2019, we entered into a short-term note payable for $17,688 bearing interest at 5.69% to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 14, 2020.

Directors' and Officers' Insurance

On July 24, 2020, we entered into a short-term note payable for $413,784 bearing interest at 5.39% 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, 2020 and were made evenly based on a straight-line amortization over an 11-month period with the final payment being made on June 28, 2021.

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.

Preferred Stock – Series C Preferred Redemption and Outstanding

During the three months ended March 31, 2021, we provided a notice of redemption, to the holder of our Series C Preferred Stock to redeem all outstanding Series C Preferred Stock (which included the dividend of 26.697 shares paid on January 28, 2021 and any accrued dividends due through the redemption date of March 13, 2021). The Series C Preferred Stock redemption amount of approximately $5.6 million was paid on March 15, 2021 and all outstanding shares of Series C Preferred Stock were cancelled.

Our Outstanding Preferred Stock

During 2017, we issued shares of Series A and Series B Preferred Stock in financing transactions (the "Preferred Stock Financings"). In connection with the Preferred Stock Financings, we filed Certificate of Designations of Preferences, Rights and Limitations of Series A and Series B Preferred Stock with the Secretary of State of the State of Florida, effective May 10, 2017 and November 8, 2017, respectively. Our currently outstanding Series A and Series B Preferred Stock and the amount of common stock that may be issued upon conversion is set forth below:

Preferred Stock Series	Outstanding Shares	Common Stock Equivalents
Series A Preferred	9,417,000	941,701
Series B Preferred	6,600,000	1,320,002

In addition, we issued warrants to purchase an aggregate of (i) 1,064,520 shares of Common Stock to the Series A holders, and (ii) 1,064,518 shares of Common Stock to the Series B holders in connection with the Preferred Stock Financings.

Except as otherwise required by law, the Series A and Series B Preferred Stock have no voting rights. However, as long as any shares of Series A and 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 A and Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A or 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 A and series B Preferred Stock, (c) increase the number of authorized shares of Series A and Series B 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 Designations), the holders of Series A and Series B 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 and 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 A and Series B Preferred Stock if all outstanding shares of Series A and Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A and Series B Preferred Stock is classified as permanent equity.

Future Capital Requirements

Our capital requirements for 2021 and for 2022 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, nonclinical testing and clinical trials, 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 Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalent, provide us with limited liquidity. We believe our existing cash and cash will allow us to fund our operating plan into the third quarter of 2022. 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 and commercialization 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 Terra CoV-2 vaccine candidate and our other product candidates, we will require additional capital. 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 Terra CoV-2 vaccine candidate at our anticipated pace, in accordance with our NIAID License and NRC License, will be 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:

- conduct preclinical research for our Terra CoV-2 vaccine product candidate, file an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- 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 Precigen;
- 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 advance our lantibiotic development or achieve milestones under our Lantibiotic ECC and licensing arrangements and the payment obligations we may have;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and

- the timing, receipt and amounts 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 stock-based compensation and valuation of warrants. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes to our critical accounting estimates during the three and six months ended June 30, 2021.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three and six months ended June 30, 2021 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 [Mike?]

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 Interim Principal 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 Interim Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal 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, 2021 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 Interim Principal 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 Interim Principal 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, 2020 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, 2020 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, 2020 filed on March 1, 2021. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption "Risk Factors" in our Annual Report on Form 10-K.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and $9.0 million and $17.5 million for the six months ended June 30, 2021 and June 30, 2020, respectively, and approximately $26.4 million and $15.6 million for the years ended December 31, 2020, and 2019, respectively. As of June 30, 2021, our accumulated deficit was approximately $164.6 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 Terra CoV-2 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 NAIAD 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. 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, 2021, will be sufficient to fund our operations as presently structured into the third quarter of 2022. 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 Terra CoV-2 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 and conduct further research and development on lantibiotics;
- 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 to meet our development needs, 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 through each phase of development;
- 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 and/or forego licensing attractive business opportunities.

If we do not continue to satisfy the NYSE American continued listing requirements, our common stock could be delisted from NYSE American.

The listing of our common stock on the NYSE American is contingent on our compliance with the NYSE American conditions for continued listing. One of the requirements for continued listing on the NYSE American, is the requirement that each issuer listing common stock or voting preferred stock, and/or their equivalents, to hold an annual meeting of shareholders no later than one year after the end of the issuer's fiscal year. The Company's annual meeting of shareholders, scheduled for June 30, 2021, at 9:00 a.m. was convened and adjourned, without any business being conducted, due to lack of the required quorum. The annual meeting of shareholders was adjourned to 4:00 p.m. (Eastern Time) on Monday, August 23, 2021.

If the Company is unable to hold an annual meeting of shareholders by December 31, 2021, it may be found to be noncompliant with the NYSE American conditions for continued listing and our common stock may be subject to delisting from the NYSE American. In the event our common stock is no longer listed for trading on the NYSE American, our trading volume and share price may decrease and we may experience further difficulties in raising capital which could materially affect our operations and financial results. Further, delisting from the NYSE American could also have other negative effects, including potential loss of confidence by partners, lenders, suppliers, employees and may have a negative impact on other outstanding agreements. Finally, delisting could make it harder for us to raise capital and sell securities.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

The information set forth below is provided in lieu of a separate Form 8-K filing pursuant to Item 5.02(e) of Form 8-K.
Annual Base Salary Increase. On August 12 2021, the Board of Directors of the Company approved an increase to the annual base salary of the Company's Interim Principal Executive Officer and Chief Financial Officer, Michael Sullivan. Mr. Sullivan's annual base salary was increased from $229,950 to $250,000, effective August 2021. No other changes to Mr. Sullivan's compensation were made.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

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

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 16th day of August, 2021.

ORAGENICS, INC.

BY: */s/ Michael Sullivan*
Interim Principal Executive Officer

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

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, 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 16th day of August, 2021

By: */s/ Michael Sullivan*

Michael Sullivan

Interim Principal 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 16th day of August, 2021

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, 2021 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Interim Principal Executive Officer

Date: August 16, 2021

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, 2021 (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 16, 2021