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, 2022.

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 8, 2022, there were 116,394,806 shares of Common Stock, $.001 par value, outstanding.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Consolidated Balance Sheets

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 17,867,483	$ 27,265,703
Other receivables	—	6,987
Prepaid expenses and other current assets	102,498	434,699
Total current assets	17,969,981	27,707,389
Property and equipment, net	109,780	45,708
Operating lease right-of-use assets	385,361	477,882
Total assets	$ 18,465,122	$ 28,230,979
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,279,598	$ 947,574
Short-term notes payable	—	303,416
Operating lease liabilities	180,824	194,270
Total current liabilities	1,460,422	1,445,260
Long-term liabilities:		
Operating lease liabilities	217,353	299,520
Total long-term liabilities	217,353	299,520
Shareholders' equity:		
Preferred stock, no par value; 50,000,000 shares authorized; 9,417,000 Series A shares, 6,600,000 Series B shares, issued and outstanding at June 30, 2022 and December 31, 2021, respectively	2,656,713	2,656,713
Common stock, $0.001 par value; 250,000,000 and 200,000,000 shares authorized at June 30, 2022 and December 31, 2021, respectively, 116,394,806 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	116,395	116,395
Additional paid-in capital	195,356,454	194,987,219
Accumulated deficit	(181,342,215)	(171,274,128)
Total shareholders' equity	16,787,347	26,486,199
Total liabilities and shareholders' equity	$ 18,465,122	$ 28,230,979

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Operations
(Unaudited)

	2022	2021	2022	2021
	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Grant revenue	$ 30,391	$ —	$ 45,474	$ —
Operating expenses:				
Research and development	3,033,182	2,467,575	7,771,244	5,728,479
General and administrative	1,044,334	1,370,393	2,375,883	3,346,969
Total operating expenses	4,077,516	3,837,968	10,147,127	9,075,448
Loss from operations	(4,047,125)	(3,837,968)	(10,101,653)	(9,075,448)
Other income (expense):				
Interest income	15,369	24,254	27,275	44,287
Interest expense	(816)	(1,033)	(4,062)	(3,601)
Local business tax	(490)	(600)	(980)	(1,200)
Miscellaneous income	369	—	11,333	670
Total other income, net	14,432	22,621	33,566	40,156
Loss before income taxes	(4,032,693)	(3,815,347)	(10,068,087)	(9,035,292)
Income tax benefit	—	—	—	—
Net loss	$ (4,032,693)	$ (3,815,347)	$ (10,068,087)	$ (9,035,292)
Basic and diluted net loss per share	$ (0.03)	$ (0.03)	$ (0.09)	$ (0.08)
Shares used to compute basic and diluted net loss per share	116,394,806	115,864,162	116,394,806	109,357,191

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Changes in Shareholders' Equity
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2021	116,394,806	$ 116,395	16,017,000.000	$ 2,656,713	$ 194,987,219	$ (171,274,128)	$ 26,486,199
Compensation expense relating to option issuances	—	—	—	—	90,247	—	90,247
Net loss	—	—	—	—	—	(6,035,394)	(6,035,394)
Balances at March 31, 2022	116,394,806	$ 116,395	16,017,000.000	$ 2,656,713	$ 195,077,466	$ (177,309,522)	$ 20,541,052
Compensation expense relating to option issuances	—	—	—	—	278,988	—	278,988
Net loss	—	—	—	—	—	(4,032,693)	(4,032,693)
Balances at June 30, 2022	116,394,806	$ 116,395	16,017,000.000	$ 2,656,713	$ 195,356,454	$ (181,342,215)	$ 16,787,347

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
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

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Cash Flows
(Unaudited)

	For the Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (10,068,087)	$ (9,035,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18,847	25,176
Gain on sale of property and equipment	(10,964)	—
Stock-based compensation expense	369,235	1,354,901
Changes in operating assets and liabilities:		
Other receivables	6,987	—
Prepaid expenses and other current assets	332,201	256,189
Accounts payable and accrued expenses	332,024	993,251
Net cash used in operating activities	(9,019,757)	(6,405,775)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	12,000	—
Purchase of property and equipment	(87,047)	—
Net cash used in investing activities	(75,047)	—
Cash flows from financing activities:		
Payments on short-term notes payable	(303,416)	(228,227)
Redemption of Series C Preferred stock	—	(5,635,672)
Proceeds from issuance of common stock for option exercise	—	267,140
Proceeds from issuance of common stock for warrant exercise	—	2,261,336
Net proceeds from issuance of common stock	—	26,676,392
Net cash provided by (used in) financing activities	(303,416)	23,340,969
Net increase (decrease) in cash and cash equivalents	(9,398,220)	16,935,194
Cash and cash equivalents at beginning of period	27,265,703	17,639,575
Cash and cash equivalents at end of period	$ 17,867,483	$ 34,574,769
Supplemental disclosure of cash flow information:		
Interest paid	$ 4,062	$ 3,601
Non-cash investing and financing activities:		
Stock dividend on Series C Preferred stock	$ —	$ 1,117,531

See accompanying notes.

Oragenics, Inc.

Notes to Consolidated Financial Statements
(Unaudited)

1. Organization

Oragenics, Inc. (the "Company" or "we") is focused on the development of the NT-CoV2-1 intranasal vaccine candidate to combat the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2") and 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, 2022 and December 31, 2021 (audited) and three and six months ended June 30, 2022 and 2021, 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, 2022, are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2022, 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, 2021, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022. 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 $10,068,087 and used cash of $9,019,757 in its operating activities during the six months ended June 30, 2022. As of June 30, 2022, the Company had an accumulated deficit of $181,342,215.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at June 30, 2022 will be sufficient to meet the business objectives as presently structured through the fourth quarter of 2022. As such, there is substantial doubt that we can continue as a going concern beyond that date.

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

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

3. Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of Oragenics, Inc. and our wholly-owned subsidiary Noachis Terra, Inc.("NTI"). 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, 2022, that have had, or are expected to have, a material impact on our consolidated financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The principal area of estimation reflected in the consolidated financial statements is stock-based compensation.

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, or warrants 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, 2022, the uninsured portion of this balance was $17,617,483. As of December 31, 2021, the uninsured portion of this balance was $27,015,703.

Grant Revenue

Grant revenues are derived from a small business innovation research grant in the amount of $250,000 (“Computer-aided Design for Improved Lantibiotics” R41GM136034. The Company recognizes grant revenue as reimbursable grant costs are incurred up to the pre-approved award limits within the budget period. The costs associated with these reimbursements are reflected as a component of research and development expenses in the accompanying consolidated statement of operations.

4. 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, 2022	For the Three Months Ended June 30, 2021	For the Six Months Ended June 30, 2022	For the Six Months Ended June 30, 2021
Research and development	$ 26,399	$ 48,761	$ 65,854	$ 79,688
General and administrative	252,589	182,379	303,381	1,275,213
Total Stock-based compensation	$ 278,988	$ 231,140	$ 369,235	$ 1,354,901

The following table summarizes the stock option activity during the six months ended June 30, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value[(1)]
Outstanding at December 31, 2021	6,724,402	$ 0.95	7.99	$ 2,773
Granted	1,382,500	0.32	—	$ —
Exercised	—	—	—	$ —
Expired	(4,500)	12.00		
Forfeited	(726,998)	0.94	—	$ —
Outstanding at June 30, 2022	7,375,404	$ 0.83	8.06	$ 72,050
Exercisable at June 30, 2022	5,952,900	$ 0.89	7.74	$ 36,300

(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, 2021 and June, 2022, respectively.

Total unrecognized compensation cost related to unvested stock options was $436,162 as of June 30, 2022 and is expected to be recognized over a weighted-average period of less than two years.

On February 25, 2022, the Company held its reconvened 2020 Annual Meeting. At the reconvened 2020Annual Meeting, the shareholders of the Company approved and ratified the Company’s 2021 Equity Incentive Plan (the “2021 Plan”) which is a successor to the Company’s 2012 Equity Incentive Plan (the “2012 Plan”).The 2021 Plan provides the aggregate number of shares of Common Stock that may be issued under the 2021 Plan will not exceed the sum of (i) 10,000,000 new shares, (ii) the number of shares remaining available for the grant of new awards under the 2012 Plan as of immediately prior to the effective date of the 2021 Plan, and (iii) certain shares subject to outstanding awards granted under the 2012 Plan that may become available for issuance under the 2021 Plan, as such shares become available from time to time. As of June 30, 2022, 9,877,306 shares of common stock are available for future awards under the 2021 Plan.

Each executive officer and non-employee director receiving equity-based awards is subject to a minimum dollar value stock ownership holding requirement with respect to the awards received as well as all prior equity awards under the Plan which requirements are intended to align the ability to sell shares with the performance of the Company’s stock price. The executive officer recipients each have a minimum dollar value stock ownership holding requirement threshold equal to two times (2x) their then base salaries below which dollar threshold they would be precluded from selling any shares of Company stock obtained from the Company under its Plan. Also, the non-employee directors are each subject to a minimum dollar value stock ownership holding requirement threshold equal to six times the annual Board retainer ($270,000) below which dollar threshold they would be precluded from selling shares of Company stock acquired from the Company under its Plan.

5. Warrants

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.

A summary of warrant activity for the year ended December 31, 2021 and the six months ended June 30, 2022 is as follows:

	Warrants	Weighted Average Price
Balance - December 31, 2020	20,513,145	$ 1.36
Granted	—	—
Exercised	(2,472,573)	0.91
Expired	—	—
Balance - December 31, 2021	18,040,572	1.42
Granted	—	—
Exercised	—	—
Expired	—	—
Balance - June 30, 2022	18,040,572	$ 1.42

The warrants outstanding as of June 30, 2022 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.

6. Short-Term Notes Payable

As of June 30, 2022 and December 31, 2021, the Company had $— and $303,416, respectively, in short-term notes payable for the financing of various insurance policies.

Products Liability Insurance

The product liability insurance policy has been renewed in subsequent periods without premium financing.

Directors' and Officers' Insurance

On July 24, 2021, the Company entered into a short-term note payable for $600,169 bearing interest at 5.34% 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, 2021 and are made evenly based on a straight-line amortization over a 10-month period with the final payment being made on May 16, 2022.

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.

7. Commitments and Contingencies

Additional Consideration-NTI Acquisition

In connection with the Company's acquisition of NTI in May of 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 $0.75 and $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding. The Company's previously issued warrants carrying an exercise price of $0.75 have expired by their terms. As a result, no additional consideration will be due to the former sole shareholder of NTI relating to these warrants.

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. See Note 9. Shareholders' Equity.

As a result of the warrant exercises in 2021, the Company paid $542,263 of additional consideration to the sole former shareholder of NTI. The additional consideration payment is included in research and development expenses.

During the three months ended June 30, 2022, no warrants were exercised that resulted in the payment of additional consideration to the sole former shareholder of NTI.

NIH License

Through NTI, the Company is a party to a Patent License and Biological Materials License Agreement (the "NIH 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 NIH 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 NIH 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 NIH 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.

NRC License

On July 26, 2021, the Company entered into a non-exclusive Technology License Agreement (the "NRC 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 NRC 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. The NRC License Agreement was subsequently amended to include the Delta and Omicron variants. In addition, the Company subsequently amended the NRC License Agreement to broaden the non-exclusive field of use to include all diseases caused by coronaviruses and any genetic variants thereof.

As consideration for the grant of the license, the Company will pay to the NRC an annual (low five digits) 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. Milestone payments range from the low five digits to high six digits. 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 NRC 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 NRC 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 NRC License Agreement.

Unless terminated earlier, the NRC License Agreement will terminate twenty (20) years from the effective date of the NRC License Agreement. Either party may terminate the NRC License Agreement, by giving written notice to the other party, if the other party defaults or is in breach of the NRC License Agreement, provided that if the defaulting party cures the breach within 60 days after the notice is given, the NRC License Agreement shall continue in full force and effect. The NRC may terminate the NRC 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 NRC 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.

Leases

Lab Facility-Alachua. 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.

Corporate Office – Tampa. 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, 2022	December 31, 2021
Weighted Average Remaining Lease Term In Years		
Operating leases	1.95	2.45
Weighted Average Discount Rate		
Operating leases	5.69%	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:		
2022	$	108,829
2023		169,656
2024		146,718
Total	$	425,203
Less: Imputed interest		(27,026)
Present value of lease liabilities	$	398,177

The cost component of operating leases is as follows:

	For the Six Months Ended June 30, 2022	For the Six Months Ended June 30, 2021
Operating lease cost	$ 114,259	$ 114,002
Short-term lease cost	1,965	782
Total lease cost	$ 116,224	$ 114,784

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

	For the Six Months Ended June 30, 2022	For the Six Months Ended June 30, 2021
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 117,350	$ 113,454

8. Shareholders' Equity

Common Stock

The Company's Board of Directors and the Company's shareholders, at its reconvened 2020 Annual Meeting on February 25, 2022, approved an amendment to our Amended and Restated Articles of Incorporation to (i) increase the number of authorized shares of common stock from 200,000,000 shares to 250,000,000 shares.

During the three and six months ended June 30, 2022, the Company issued no shares of common stock.

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 At-The-Market Program which generated gross proceeds of approximately $27.8 million 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.

Preferred Stock

Series C Non-Voting, Non-Convertible, 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, 2021 filed on March 24, 2022.

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 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 including coronaviruses and multidrug-resistant organisms. Our lead product (NT-CoV2-1) is an intranasal vaccine candidate to prevent coronavirus disease 2019 ("COVID-19") from the SARS-CoV-2 virus and variants thereof. The NT-CoV2-1 program leverages coronavirus spike protein research licensed from the National Institute of Health and the National Research Council of Canada with a focus on reducing viral transmission and offering a more patient-friendly intranasal administration. Our lantibiotics program features a novel class of antibiotics against bacteria that have developed resistance to commercial antibiotics.

Our SARS-CoV-2 Vaccine Product Candidate - NT-CoV2-1

Following our May 2020 acquisition of one hundred percent (100%) of the total issued and outstanding common stock of Noachis Terra, Inc. ("Noachis Terra") we are focused on the development and commercialization of a vaccine product candidate to provide long-lasting immunity from SARS-CoV-2, which causes 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. Since the acquisition we have conducted testing in animal models, including SARS-CoV-2 challenge studies in hamsters, using specific formulations for intramuscular administration (our Terra CoV-2 vaccine candidate) and intranasal administration (our NT-CoV2-1 vaccine candidate), both based on the NIAID pre-fusion stabilized spike protein antigens. Following consideration of a number of factors, including but not limited to the competitive landscape, we determined to bring the intranasal vaccine candidate NT-CoV2-1, into further development due to the greater differentiation versus current COVID-19 vaccines and the potential benefits of intranasal over intramuscular administration. We believe these benefits could include a higher reduction of transmission of SARS-CoV-2 and would offer a needle-free delivery option. We therefore are currently focusing our development efforts on our more highly differentiated NT-CoV2-1 vaccine candidate.

On July 26, 2021, we entered into a licensing agreement with the National Research Council ("NRC") that enables us to pursue the development of next-generation vaccines against the SARS-CoV-2 virus and its variants. The license was subsequently amended to include the Omicron variant to broadened the non-exclusive field of use to include all diseases caused by coronaviruses and any genetic variants thereof and to add a research protocol developed by the NRC and reagents as part of the NRC Technology licensed by us. The NRC technologies, in combination with the licensed technologies from the U.S. NIH used in our NT-CoV2-1 vaccine candidate, 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, are expected to enable expedited evaluation of SARS-CoV-2 antigen candidates in pre-clinical and clinical studies.

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, which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). In late July of 2022, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 566 million and the number of deaths directly attributed to COVID-19 have exceeded 6.4 million. Pfizer/BioNTech received FDA approval for their COVID-19 vaccines in August of 2021 and the Moderna vaccine in January 2022. The Janssen vaccine is currently available in the United States under Emergency Use Authorizations ("EUA") by the FDA. In July 2022, the FDA granted EUA for the Novavax COVID-19 vaccine as well. The overall disease burden from COVID-19 has continued to increase in the U.S. despite 92% of those age 65 or older being fully vaccinated and 72% of those age 5 or older. Current vaccines have reduced the rates of hospitalization and death due to COVID-19 in vaccinated individuals, but the transmission levels even in vaccinated individuals has allowed SARS-CoV-2 variants to continue to circulate. We believe given the size of the worldwide pandemic that even with additional vaccines available in the months ahead, there will be demand for the highly differentiated NT-CoV2-1 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license and with our NRC license and our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health issue. We believe our NT-CoV2-1 vaccine holds the possibility of playing an important role in addressing this issue.

Coronaviruses, such as SARS-CoV-2, possess signature protein spikes on their outer capsule. Our 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. Spike protein antigens stabilized in the pre-fusion state have been used successfully in the leading COVID-19 vaccines from Pfizer/BioNTech and Moderna, which we believe reduces the risk of using the same approach in our NT-CoV2-1 vaccine candidate. The Company is currently producing Phase 1 clinical materials based on the pre-fusion protein stabilization technology licensed from the NIH as well as additional antigen design technologies licensed from the NRC.

We entered into both a material transfer agreement and a non-exclusive research license agreement with Inspirevax for the use of intranasal mucosal adjuvants in our NT-CoV2-1 vaccine candidates. Regarding the intranasal mucosal adjuvants of interest, 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 non-exclusive license agreement allows for the collaboration and research 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 NT-CoV2-1 vaccine containing Inspirevax's intranasal mucosal adjuvant BDX301 has been studied in pre-clinical animal studies, including hamster viral challenge studies and mouse immunogenicity studies. A rabbit toxicology study has been initiated and is required for regulatory approval prior to the Phase 1 clinical study.

We began pre-clinical 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. On August 30, 2021, we announced the successful completion of these mouse immunogenicity studies that supported further development using either the intramuscular or intranasal routes of administration. A hamster challenge study was initiated in September of 2021 to assess inhibition of viral replication using adjuvants specific for intramuscular and intranasal administration. In December of 2021, we announced that both formulations generated robust immune responses and reduced the SARS-CoV-2 viral loads to undetectable levels in the nasal passages and lungs five days following a viral challenge. By contrast, hamsters in the control groups that had received saline or adjuvants alone had no detectable immune response and substantial viral loads. The vaccines delivered by intranasal and intramuscular routes generated immune responses as measured by multiple assays. On June 14, 2022, we announced that the results of these studies were published in Nature Scientific Reports.

In March of 2022, following a positive assessment of a rabbit-based pilot study, we initiated a Good Laboratory Practice toxicology study to evaluate the safety profile and immunogenicity of NT-CoV2-1 in rabbits. This important preclinical study is designed to provide data required to advance our intranasal vaccine candidate into human clinical studies. While the study has concluded, we are completing the full set of toxicology data which will be needed to support the filing of an IND application for NT-CoV2-1. Based on our previous preclinical results, we are encouraged that this study may further support our intranasal development path.

While we previously had a Type B Pre-IND Meeting with the FDA on our intramuscular vaccine product candidate, we again met with the FDA in a Type B Pre-IND Meeting request to discuss our intranasal vaccine product candidate. As a result of this meeting, the FDA indicated that the Company could file an IND application for NT-CoV2-1 following the availability of the final GLP toxicology report for inclusion in the IND.

We believe the benefits of our NT-CoV2-1 vaccine product candidate through its intranasal delivery mechanism to be:

- **Targeted Mucosal Immunity** – Conventional injectable vaccines are poor inducers of mucosal immunity, whereas intranasal immunization can induce strong mucosal immunity by enhancing the immune response at the entry sites of mucosal pathogens. When the SARS-CoV-2 virus enters the nasal cavity, the respiratory epithelial layer is the first barrier against viral infection. The intranasal route of vaccination provides two additional layers of protection over intramuscular shots because (i) it produces immunoglobulin A and resident memory B and T cells in the respiratory mucosa that are an effective barrier to infection at those sites, and (ii) cross-reactive resident memory B and T cells can respond earlier than other immune cells should a viral variant start an infection.

- **Needle-Free Administration** – As an obvious benefit, intranasal administration means needle-free delivery, resulting in meaningful differentiation for children and needle-phobic populations, improved compliance and the potential for self-administration.

- **Storage & Transport** – The currently available mRNA-based vaccines have been delivered globally via stringent storage and transport requirements that strain distribution logistics under the best of circumstances. A key benefit of our NT-CoV2-1 vaccine candidate is a significantly reduced handling burden, allowing transport at a more manageable refrigeration temperature (5°C) that improves access globally including remote and under-vaccinated geographies.

- **Durability** – Broad initial success with mRNA vaccines has significantly diminished COVID-19's impact and death, but the trade-off has been fleeting efficacy. By benefitting from the immunological properties of the hybrid NIH/NRC construct, NT-CoV2-1 is potentially much more durable and long-lasting than currently available mRNA-based therapies.

Through assessment of a variety of factors including our pre-clinical testing to date, the expected benefits noted above, evolving variants and available vaccines in use, we determined to focus our development efforts on the intranasal delivery of our vaccine product candidate, NT-CoV2-1, which we believe is more highly differentiated than the currently available and late-stage COVID-19 vaccines. We expect to file an IND application with the FDA upon completion of our pending toxicology study and to thereafter commence a Phase 1 clinical study with NT-CoV2-1, the protocol for which is currently under development.

In parallel with our pursuit of an IND for a US-based Phase 1 study, we are exploring regulatory approval of an equivalent safety and immunogenicity study with Health Canada through the submission of a Clinical Trial Application ("CTA") with feedback expected by the end of 2022. Given Health Canada's experience with related adjuvants to that used in NT-CoV2-1 and the growing urgency for nasal vaccines, we believe this parallel regulatory path remains a viable route for maintaining our development timelines.

We expect to use our currently available cash resources to continue to advance the development of NT-CoV2-1 through IND-enabling studies and commencement of a Phase 1 clinical 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 - Oragenics Derived Compound (ODC-x)

Members of our scientific team discovered that a certain bacterial strain of *Streptococcus mutans,* produces Mutacin 1140 (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. Over 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.

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.

The timing of the filing of an IND regarding any future lantibiotic 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.

In October 2021, we were awarded a small business innovation research grant in the amount of $250,000 ("Computer-aided Design for Improved Lantibiotics", R41GM136034) for the Company's continued research and development of lantibiotics, including its collaborative program with the Biomolecular Sciences Institute at Florida International University (FIU). The grant provides the Company with funding to develop novel lantibiotics for the treatment of ESKAPE pathogens (defined as *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter spp.*).

Product Candidates.

Through our wholly-owned subsidiary, Noachis Terra, we began the research and development stage for our new Terra CoV-2 and NT-CoV2-1 vaccine product candidates. 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. We also hold a non-exclusive license with the NRC that enables us to pursue the rapid development of next-generation vaccines against the SARS-CoV-2 (the "NIH License") virus and its variants (the "NRC License" and together with the NIH License the License Agreements.

Additionally, we are developing semi-synthetic lantibiotic analogs that may be effective against systemic Gram-positive multidrug infections, and analogs that may be effective in treating Gram-negative 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
NT-CoV2-1	Intranasal vaccine candidate (recombinant protein + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
Antibiotics	Semi-synthetic analogs of MU1140: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Pre-clinical

Our Business Development Strategy

Success in the biopharmaceutical and product development industry relies on the continuous development of novel product candidates. Most product candidates do not make it past the clinical development stage, 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.

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, the emergence of any new variant strains of COVID-19, and the impact on local, regional, national and international markets.

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 NT-CoV2-1 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. Clinical research costs consist of clinical trials, manufacturing services, regulatory activities all of which are largely provided by third parties. Nonclinical research and development costs consist of our research activities, research activities provided by third parties, our own nonclinical studies, nonclinical studies provided by third parties, the acquisition of in process research and development, 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 $7,771,244 and $5,728,479 for the six months ended June 30, 2022 and 2021, 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 program and the License Agreements as to the planning and timing of our research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, we expect overall research and development expenses to increase as a result of our vaccine product candidate and to remain relatively constant with respect to our lantibiotic program. 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, gain on sale of property and equipment, 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

At December 31, 2021, the Company has federal and state tax net operating loss carryforwards of $145,260,353. Federal and state tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037 and are not subject to taxable income limitations. Federal tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but are subject to taxable income limitation pursuant to the Tax Cuts and Jobs Act that was enacted on December 22, 2017. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. The Company also has federal research and development tax credit carryforwards of $4,027,180. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2041 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, 2022 and 2021

Grant revenue. Grant revenue was $30,391 for the three months ended June 30, 2022 compared to $-0- for the three months ended June 30, 2021; an increase of $30,391, or 100.0%. This increase was attributable to the award of a small business innovation research grant.

Research and Development. Research and development expenses were $3,033,182 for the three months ended June 30, 2022 compared to $2,467,575 for the three months ended June 30, 2021, an increase of $565,607 or 22.9%.

The table below provides a breakdown of our research and development expense for the periods for our current development programs:

	For the Three Months Ended June 30, 2022	For the Three Months Ended June 30, 2021
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	297,520	304,311
Vaccine Development Expense		
Clinical Research	864,367	-
Non-clinical research and development activities	1,871,295	2,163,264
Total Research and Development expense	**$ 3,033,182**	**$ 2,467,575**

This increase was primarily due to increases in costs associated with the NT-CoV2-1 vaccine program, supplies and equipment costs, and rent and utilities costs of $572,398, $34,292, and $18,735, respectively. These increases were partially offset by decreases in costs associated with salaries and costs associated with our lantibiotic program of $29,967, and $23,254, respectively. The increase in research and development expenses attributable to the vaccine development program related to our taking the requisite preclinical steps to be in a position to submit an Initial New Drug Application to the FDA or other regulatory agency, including conducting toxicology studies in mice, hamsters, and rabbits, enablement of COVID 19 variants, securing an adjuvant, assay testing, stability and release testing and preparing the elements necessary for manufacturing of our vaccine product candidate in order to be in a position to move forward with a Phase 1 and Phase 2 clinical studies.

General and Administrative. General and administrative expenses were $1,044,334 for the three months ended June 30, 2022 compared to $1,370,393 for three months ended June 30, 2021, a decrease of $326,059 or 23.8%. This decrease was primarily due to decreases in salaries, filing fees and registration costs, and board costs of $252,448, $134,054, and $33,687. These decreases were offset by increases in non-employee stock-based compensation, and insurance costs of $54,704 and $37,431, respectively.

Other Income. Other income, net was $14,432 for the three months ended June 30, 2022 compared to $22,621 for the three months ended June 30, 2021, resulting in a net change of $8,189. The net change was primarily attributable to a decrease in interest income of $8,885.

Results of Operations for the Six Months Ended June 30, 2022 and 2021

Grant revenue. Grant revenue was $45,474 for the six months ended June 30, 2022 compared to $-0- for the six months ended June 30, 2021; an increase of $45,474, or 100.0%. This increase was attributable to the award of a small business innovation research grant.

Research and Development. Research and development expenses were 7,771,244 for the six months ended June 30, 2022 compared to 5,728,479 for the six months ended June 30, 2021, an increase of $2,042,765 or 35.7%.

The table below provides a breakdown of our research and development expense for the periods for our current development programs:

	For the Six Months Ended June 30, 2022	For the Six Months Ended June 30, 2021
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	688,557	595,383
Vaccine Development Expense		
Clinical Research	1,955,117	-
Non-clinical research and development activities	5,127,570	5,133,096
Total Research and Development expense	**$ 7,771,244**	**$ 5,728,479**

This increase was primarily due to increases in costs associated with the NT-CoV2-1 vaccine program, supplies and equipment costs, bonus costs, costs associated with our lantibiotic ECC, patent costs, and rent and utilities costs, of $2,491,852, $44,490, $39,060, $27,966, $26,745, and $18,891, respectively. These increases were partially offset by decreases in costs associated with consideration relating to the acquisition of Noachis Terra, Inc., and salaries of $542,261, and $71,603, respectively. The increase in research and development expenses attributable to the vaccine development program related to our taking the requisite preclinical steps to be in a position to submit an Initial New Drug Application to the FDA or other regulatory agency, including conducting toxicology studies in mice, hamsters, and rabbits, enablement of COVID 19 variants, securing an adjuvant, assay testing, stability and release testing and preparing the elements necessary for manufacturing of our vaccine product candidate in order to be in a position to move forward with a Phase 1 and Phase 2 clinical studies.

General and Administrative. General and administrative expenses were $2,375,883 for the six months ended June 30, 2022 compared to $3,346,969 for six months ended June 30, 2021, a decrease of $971,086 or 29.0%. This decrease was primarily due to decreases in non-employee stock-based compensation, salaries, employee benefits, stock-based compensation costs, and payroll taxes of $945,141, $336,103, $27,233, $26,692, and $21,091. These decreases were offset by increases in costs associated with filing fees and registration costs, insurance, bonus, and legal costs of $216,742, $75,572, and $52,254, respectively.

Other Income. Other income, net was $33,566 for the six months ended June 30, 2022 compared to $40,156 for the six months ended June 30, 2021, resulting in a net change of $6,590. The net change was primarily attributable to a decrease in interest income of $16,273. and an increase in the gain on sale of property and equipment of $10,964.

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, 2022 and June 30, 2021 our operating activities used cash of $9,019,757, and $6,405,775, 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 $16,509,559 and $26,262,129 at June 30, 2022 and December 31, 2021, respectively.

During the six months ended June 30, 2022 and June 30, 2021, our investing activities used cash of $(75,047) and $-0- respectively. The cash used by investing activities during the six months ended June 30, 2022, was primarily due to the purchase of property and equipment net of the proceeds from the sale of property and equipment.

During the six months ended June 30, 2022 and June 30, 2021, our financing activities used and provided cash of $(303,416) and $23,340,969 respectively. The cash used by and provided in financing activities during the six months ended June 30, 2022 and June 30, 2021, was primarily due to payments on short term notes payable, the sales of common stock, the exercise of warrants, and the redemption of the Series C Preferred stock.

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, NT-CoV2-1 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, NT-CoV2-1 and our lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

At-the- Market ("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. 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") of which $9,671,869 remains available under our 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

The product liability insurance policy has been renewed in subsequent periods without premium financing.

Directors' and Officers' Insurance

On July 24, 2021, we entered into a short-term note payable for $600,169 bearing interest at 5.34% 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, 2021 and are made evenly based on a straight-line amortization over a 10-month period with the final payment being made on May 16, 2022.

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.

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 (as defined in the Certificate of Designations) 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. Each of the Series A and Series B Preferred Stock have redemption rights to the extent we have funds legally available therefor, at any time after the fifth anniversary of the original issue date of the applicable Series A and Series B Preferred Stock. We have the right to redeem all or any portion of the outstanding shares of Series A and Series B Preferred Stock at the original issue price by providing at least seventy five (75) days written notice of such redemption to all holders of the then outstanding shares of Series A and Series B Convertible Preferred Stock.

Future Capital Requirements

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

Our current available cash and cash equivalents, provide us with limited liquidity. We believe our existing cash and cash will allow us to fund our operating plan through the fourth 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 NT-CoV2-1 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 NT-CoV2-1 vaccine candidate at our currently anticipated pace, in accordance with our License agreements, is dependent upon our ability to secure additional capital resources through these funding opportunities or an alternative capital raise, such as an equity or debt financing or other strategic business collaboration. Moreover, the global impact of COVID-19 could further impact our need for additional capital if we experience delays in our anticipated timelines or achievement milestones.

Because of the numerous risks and uncertainties associated with research, development and clinical testing of our product candidates, we are unable to estimate the exact amounts of our working capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- conducting preclinical research for our NT-CoV2-1vaccine product candidate, filing an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- our ability to partner or collaborate with third parties;
- 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;
- 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 License Agreements 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 area of estimation reflected in the consolidated financial statements is stock-based compensation. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2021 There have been no material changes to our critical accounting estimates during the three and six months ended June 30, 2022.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three and six months ended June 30, 2022 that have had or are expected to have an impact on our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our 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 Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our 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, 2022 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 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 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, 2021 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, 2021 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, 2021 filed on March 24, 2022. 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 $10.1 million and $9.0 million for the six months ended June 30, 2022 and June 30, 2021, respectively, and approximately $15.7 million and $26.4 million for the years ended December 31, 2021, and 2020, respectively. As of June 30, 2022, our accumulated deficit was approximately $181.3 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 NT-CoV2-1 vaccine product candidate and the research and development of our product candidates in the area of lantibiotics ("Lantibiotics Program") will continue to increase the level of our overall expenses significantly going forward. Additionally, our License Agreements 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, 2022, will be sufficient to fund our operations as presently structured through the fourth 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 NT-CoV-2-1 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 level of research and development investment budgeted to develop our current and future product candidates through each phase of development;
- the timing, scope, progress, results and cost of research and development, testing, screening, manufacturing, preclinical and non-clinical studies and clinical trials, including any impacts related to the COVID-19 pandemic;;
- 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 vaccine and technological and market developments;
- our interaction and relationship with the FDA, or other, regulatory agencies; and
- changes in regulatory policies or laws that affect our operations.

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

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.4	6/26/18	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.5	2/28//22	
3.6	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.7	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.8	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.9	Third Amendment to Bylaws	8-K	001-32188	3.9	2/28/22	
10.1	National Research Council (NRC) Canada Technology License Agreement (dated July 26, 2021) and Amendment One (dated September 2, 2021).*	10-Q	001-32188	10.0	11/15/21	
10.2	NRC Technology License Amendment 2	10-K	001-32188	10.6	3/24/22	
10.3	NRC Technology License Amendment 3	10-K	001-32188	10.7	3/24/22	
10.4	NRC Technology License Amendment 4					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	Inline XBRL Instance Document					
101.SCH	Inline XBRL Taxonomy Extension Schema					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document					

* Confidential treatment has been granted as to certain portions of this exhibit pursuant to Rule 406 of the Securities Act of 1933, as amended, or Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 9th day of August, 2022.

ORAGENICS, INC.

BY: */s/ Kimberly Murphy*
Kimberly Murphy, President and Chief Executive Officer and Principal Executive Officer

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

National Research Council Canada | Conseil national de recherches Canada

Amendment 4 to Technology License Agreement

BUSINESS CONFIDENTIAL – PROTECTED B

THIS IS AN AMENDING AGREEMENT (hereinafter referred to as the "Amendment #4")

BETWEEN: NATIONAL RESEARCH COUNCIL OF CANADA (called **"NRC"**)

a Departmental Corporation" forming part of the Government of Canada, which corporation was created by Act of Parliament, R.S.C. 1985, c. N-15 whose head office address is: 1200 Montreal Road, Ottawa, Ontario K1A 0R6 Canada

Human Health Therapeutics (HHT) Research Centre located at:
6100 Royalmount Avenue, Montreal, Quebec H4P 2R2 Canada

Scientific contacts:	**Yves Durocher**	yves.durocher@cnrc-nrc.gc.ca
Business contact:	**Alexandre Serrano** –	alexandre.serrano@cnrc-nrc.gc.ca

AND: **ORAGENICS, INC.** (called the **"Licensee")**

a corporation under the laws of the state of Florida, the United States of America whose address is: 4902 Eisenhower Boulevard – Suite 125- Tampa, Florida, 33634, U.S.A. **Contact: Michael Sullivan – Email:** msullivan@oragenics.com

(Hereinafter jointly referred to as "the **Parties**" and each, a "**Party**")

WHEREAS the Parties entered into a Technology License Agreement signed by NRC on July 26, 2021 [NRC ref. #A-0039781] (called the **"Original Agreement"**) by which NRC granted a licence for internal R&D and Commercial purposes to the Licensee.

WHEREAS the Parties wish to amend the Original Agreement.

IN CONSIDERATION of the mutual covenants hereunder, the Parties agree as follows:

1. The Original Agreement shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Original Agreement.

2. The Parties hereby agree to add the following definition to the Original Agreement:

   1.36 "**Additional Protocol**" means a research protocol developed by the NRC "ELISA titer assay for qualifying Wuhan spike protein productivity" that the NRC agrees to consider part of the NRC Technology subject to the full payment of the Additional Protocol Fees.

3. The Parties hereby agree to add the following definition to the Original Agreement:

   1.37 "**Additional Protocol Fees**" means a one-time payment of $50,000 USD paid by the Licensee to the NRC for the transfer of the Additional Protocol and a sample of Reagents.

4. The Parties hereby agree to add the following definition to the Original Agreement:

   1.38 "**Reagents**" means 3mg of research grade recombinant ACE2 receptor protein and 15uL of research grade anti-SARS-CoV2 llama serum that the NRC agrees to consider part of the NRC Technology. For clarity, any additional Reagents to be requested by the Licensee shall be subject to the payment of the then applied NRC's standard fees.

5. The Parties hereby agree to replace the definition of the NRC Technology (Section 1.13 in the Original Agreement) in its entirety with the following definition:

   "**NRC Technology**" means the NRC inventions (not necessarily patentable), Patents, trade secrets Know-How, copyright, biological material, designs, and/or technical information created by or on behalf of the NRC relating to the Stable Cells, and if available, NRC's protocols, Additional Protocol and Reagents, processes or methods for the production of Drug Substance.

6. The Parties hereby agree to add the following section to the Original Agreement:

   2.6.3 **Delivery of Reagents**: Upon signing this Amendment #4 and the Licensee's full payment of the Additional Protocol Fees, the NRC shall within thirty (30) days, transfer the Reagents and the Additional Protocol to the Licensee.

7. The Parties hereby agree to add the following section to the Original Agreement:

   3.22 **Additional Protocol Fees payment**: Upon signing this Amendment #4, the Licensee shall within thirty (30) days, pay to the NRC the Additional Protocol Fees.

8. This Agreement may be executed in one or more counterparts and by the difference parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one valid and binding Agreement. A portable document format (PDF) copy of an executed counterpart signature page will be as valid as an originally executed counterpart for purposes of signing this Agreement.

SIGNED by the licensee at Tampa, Florida, U.S.A.

ORAGENICS, INC.

Date: 07/05/2022

Per: */s/ Kimberly Murphy*
CEO, President

SIGNED by the **NRC** at Ottawa, Ontario, Canada

NATIONAL RESEARCH COUNCIL OF CANADA

Date: 07/06/2022

Per: */s/ Susan Twine, A*
Director General
Human Health Therapeutics Research Centre

Exhibit 31.1

CERTIFICATION

I, Kimberly Murphy, 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 9th day of August, 2022

By: */s/ Kimberly Murphy*
Kimberly Murphy
President and Principal Executive Officer

Exhibit 31.2

CERTIFICATION

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 9th day of August, 2022

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

Exhibit 32.1

Certification of Principal 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, 2022 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Kimberly Murphy, 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/ Kimberly Murphy

Name: Kimberly Murphy
President and Principal Executive Officer

Date: August 9, 2022

Exhibit 32.2

Certification of Principal 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, 2022 (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
Principal Financial Officer

Date: August 9, 2022