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 September 30, 2021.

OR

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

For the transition period from_____ to _____

Commission File Number: 001-32188

ORAGENICS,INC.
(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities and Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, non-accelerated filer, a smaller reporting company, or an emerging growth company. See definition of "accelerated filer", "large accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

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 November 12, 2021, there were116,394,806 shares of Common Stock, $.001 par value, outstanding.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.

Consolidated Balance Sheets

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 29,948,892	$ 17,639,575
Prepaid expenses and other current assets	586,519	343,106
Total current assets	30,535,411	17,982,681
Property and equipment, net	32,704	42,713
Operating lease right-of-use assets	523,143	655,138
Total assets	$ 31,091,258	$ 18,680,532
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,523,197	$ 937,020
Short-term notes payable	482,258	228,227
Operating lease liabilities	190,181	176,900
Total current liabilities	2,195,636	1,342,147
Long-term liabilities:		
Operating lease liabilities	349,199	493,790
Total long-term liabilities	349,199	493,790
Shareholders' equity:		
Preferred stock, no par value; 50,000,000 shares authorized; 9,417,000 and 9,417,000 Series A shares, 6,600,000 and 6,600,000 Series B shares, -0- and 133.483 Series C shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2,656,713	7,174,854
Common stock, $0.001 par value; 200,000,000 shares authorized; 116,394,806 and 91,766,928 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	116,395	91,767
Additional paid-in capital	194,754,867	164,022,957
Accumulated deficit	(168,981,552)	(154,444,983)
Total shareholders' equity	28,546,423	16,844,595
Total liabilities and shareholders' equity	$ 31,091,258	$ 18,680,532

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 3,547,321	$ 3,498,361	$ 9,275,800	$ 18,755,013
General and administrative	847,134	1,010,006	4,194,103	3,337,422
Total operating expenses	4,394,455	4,508,367	13,469,903	22,092,435
Loss from operations	(4,394,455)	(4,508,367)	(13,469,903)	(22,092,435)
Other income (expense):				
Interest income	17,760	16,292	62,047	77,302
Interest expense	(7,053)	(3,885)	(10,654)	(6,478)
Local business tax	2	(600)	(1,198)	(1,800)
Miscellaneous income	—	—	670	1,795
Total other income, net	10,709	11,807	50,865	70,819
Loss before income taxes	(4,383,746)	(4,496,560)	(13,419,038)	(22,021,616)
Income tax benefit	—	—	—	—
Net loss	$ (4,383,746)	$ (4,496,560)	$ (13,419,038)	$ (22,021,616)
Basic and diluted net loss per share	$ (0.04)	$ (0.08)	$ (0.12)	$ (0.42)
Shares used to compute basic and diluted net loss per share	116,262,938	59,670,038	111,748,586	52,706,277

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, 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
Compensation expense relating to option issuances	—	—	—	—	100,769	—	100,769
Issuance of common stock from option exercise	200,000	200	—	—	95,800	—	96,000
Net loss	—	—	—	—	—	(4,383,746)	(4,383,746)
Balances at September 30, 2021	116,394,806	116,395	16,017,000	2,656,713	194,754,867	(168,981,552)	28,546,423

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	**Amount**	**Shares**	**Amount**	**Capital**	**Deficit**	**Equity**
Balances at December 31, 2019	46,124,803	$ 46,125	16,017,113.941	$ 6,513,396	$ 138,024,957	$ (127,352,826)	$ 17,231,652
Compensation expense relating to option issuances	—	—	—	—	865,110	—	865,110
Series C dividend	—	—	19.542	661,458	—	(661,458)	—
Net loss	—	—	—	—	—	(5,187,760)	(5,187,760)
Balances at March 31, 2020	46,124,803	$ 46,125	16,017,133.483	$ 7,174,854	$ 138,890,067	$ (133,202,044)	$ 12,909,002
Compensation expense relating to option issuances	—	—	—	—	157,145	—	157,145
Issuance of common stock from warrant exercise	38,000	38	—	—	28,462	—	28,500
Issuance of common stock and warrants for the acquisition of Noachis Terra	9,200,000	9,200	—	—	8,021,499	—	8,030,699
Net loss	—	—	—	—	—	(12,337,296)	(12,337,296)
Balances at June 30, 2020	55,362,803	$ 55,363	16,017,133.483	$ 7,174,854	$ 147,097,173	$ (145,539,340)	$ 8,788,050
Compensation expense relating to option issuances	—	—	—	—	194,953	—	194,953
Issuance of common stock from warrant exercise	5,642,114	5,642	—	—	5,148,260	—	5,153,902

Net loss	—	—	—	—	—	(4,496,560)	(4,496,560)
Balances at September 30, 2020	61,004,917	$ 61,005	16,017,133.483	$ 7,174,854	$ 152,440,386	$ (150,035,900)	$ 9,640,345

See accompanying notes.

Oragenics, Inc.

Consolidated Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (13,419,038)	$ (22,021,616)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	34,817	38,847
Stock-based compensation expense	1,455,670	1,217,208
Stock issued for purchase of Noachis Terra	—	8,030,699
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(243,413)	498,200
Accounts payable and accrued expenses	586,177	(1,084,621)
Net cash used in operating activities	(11,585,787)	(13,321,283)
Cash flows from investing activities:		
Purchase of property and equipment	(24,123)	—
Net cash used in investing activities	(24,123)	—
Cash flows from financing activities:		
Borrowings under short-term notes payable	600,169	132,088
Payments on short-term notes payable	(346,138)	(217,588)
Redemption of Series C Preferred stock	(5,635,672)	—
Proceeds from issuance of common stock for stock option exercise	363,140	—
Proceeds from issuance of common stock for warrant exercise	2,261,336	5,182,402
Net proceeds from issuance of common stock	26,676,392	—
Net cash provided by financing activities	23,919,227	5,096,902
Net increase (decrease) in cash and cash equivalents	12,309,317	(8,224,381)
Cash and cash equivalents at beginning of period	17,639,575	18,267,994
Cash and cash equivalents at end of period	$ 29,948,892	$ 10,043,613
Supplemental disclosure of cash flow information:		
Interest paid	$ 10,654	$ 4,245
Non-cash investing and financing activities:		
Stock dividend on Series C preferred stock	$ 1,117,531	$ 661,458

See accompanying notes.

Oragenics, Inc.

Notes to Consolidated Financial Statements
(Unaudited)

1. Organization

Oragenics, Inc. (formerly known as Oragen, Inc.) (the "Company" or "we") was incorporated in November, 1996; however, operating activity did not commence until 1999. We are focused on the creation of the Terra CoV-2 immunization product candidate to combat the novel coronavirus pandemic and the further development of effective treatments for novel antibiotics against infectious disease.

2. Basis of Presentation

The accompanying unaudited interim consolidated financial statements as of September 30, 2021 and December 31, 2020 (audited) and three and nine months ended September 30, 2021 and 2020, have been prepared in accordance with accounting principles generally accepted in the United States of America ("US GAAP") for interim consolidated financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period ended September 30, 2021, are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2021, or any future period.

These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2020, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 1, 2021. The Company has incurred recurring losses and negative cash flows from operations since inception. To date, the Company has not generated significant revenues from operations. The Company incurred a net loss of $13,419,038 and used cash of $11,585,787 in its operating activities during the nine months ended September 30, 2021. As of September 30, 2021, the Company had an accumulated deficit of $168,981,552.

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

The Company's ability to continue operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations,

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

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

3. Significant Accounting Policies

Basis of Consolidation

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

New Accounting Standards

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

Recently Issued Accounting Pronouncements

Income Taxes

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

Use of Estimates

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

Stock-Based Payment Arrangements

Generally, all forms of stock-based payments, including stock option grants, and warrants are measured at their fair value on the awards' grant date using a Black-Scholes pricing model. Stock-based compensation awards issued to non-employees for services rendered are recorded at the fair value of the stock-based payment. The expense resulting from stock-based payments are recorded in research and development expense or general and administrative expense in the consolidated statement of operations, depending on the nature of the services provided. Stock-based payment expense is recorded over the requisite service period in which the grantee provides services to us. To the extent the stock option grants, warrants, or restricted stock grants do not vest at the grant date they are subject to forfeiture.

Stock-Based Compensation

US GAAP requires all stock-based payments to employees, including grants of employee stock options, to be recognized in the consolidated financial statements based on their fair values as of the grant date. Stock-based compensation expense is recorded over the requisite service period in which the grantee provides services to us, to the extent the options do not vest at the grant date and are subject to forfeiture. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met. In connection with adopting ASU 2016-09, the Company made an accounting policy election to account for forfeitures in compensation expense as they occur.

Warrants

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

Net Loss Per Share

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

Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of September 30, 2021, the uninsured portion of this balance was $29,698,892. As of December 31, 2020, the uninsured portion of this balance was $17,389,575.

5. Stock-based Compensation

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

	For the Three Months Ended September 30, 2021	For the Three Months Ended September 30, 2020	For the Nine Months Ended September 30, 2021	For the Nine Months Ended September 30, 2020
Research and development	$ 38,946	$ 46,584	$ 118,634	$ 194,431
General and administrative	61,823	148,369	1,337,036	1,022,777
Total Stock-based compensation	$ 100,769	$ 194,953	$ 1,455,670	$ 1,217,208

The following table summarizes the stock option activity during the nine months ended September 30, 2021:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value[(1)]
Outstanding at December 31, 2020	5,801,349	$ 0.90	8.52	$ 2,773
Granted	1,720,000	$ 1.19	—	$ —
Exercised	(756,540)	$ 0.48	—	$ —
Forfeited	(512,967)	$ 1.65	—	$ —
Outstanding at September 30, 2021	6,251,842	$ 1.00	7.32	$ 460,844
Exercisable at September 30, 2021	5,396,839	$ 1.02	7.10	$ 410,777

(1)The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as of December 31, 2020 and September 30, 2021, respectively.

Total unrecognized compensation cost related to unvested stock options was $414,571 as of September 30, 2021 and is expected to be recognized over a weighted-average period of less than two years.

As of September 30, 2021, 1,000,868 shares of common stock are available for future awards under the 2012 Equity Incentive Plan (the "Plan").

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

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

6. Warrants

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

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

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

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

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

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

The warrants outstanding as of September 30, 2021 are as follows:

Exercise Price	Warrants Outstanding	Expiration Date
$ 3.10	48,387	9/19/2022
$ 2.00	900,000	4/10/2023
$ 3.10	462,106	5/10/2024
$ 3.10	602,414	7/25/2024
$ 3.10	1,064,518	11/8/2024
$ 1.00	3,174,500	7/17/2025
$ 0.90	2,588,647	3/25/2024
$ 1.25	9,200,000	5/1/2025
	18,040,572	

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

7. Short-Term Notes Payable

As of September 30, 2021 and December 31, 2020, the Company had $482,258 and $228,227, respectively, in short-term notes payable for the financing of various insurance policies.

Products Liability Insurance

On March 10, 2019, the Company entered into a short-term note payable for $17,688 bearing interest at 5.69% per annum to finance the product liability insurance. Principal and interest payments on this note began April 10, 2019 and are made evenly based on a straight-line amortization over an 11-month period with the final payment being made on February 14, 2020. 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 due on May 24, 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.

8. Commitments and Contingencies

Additional Consideration-NTI Acquisition. In connection with the Company's acquisition of NTI on May 1, 2020, the Company is obligated to pay the former sole shareholder of NTI contingent consideration based upon the exercise of certain of the Company's outstanding warrants as follows: (i) twenty percent (20%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $0.90 and (ii) forty-five percent (45%) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $1.00, in each case, for so long as the warrants remain outstanding.

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

NIH License

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

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

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

NRC License

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

the Company.

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

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

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

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

The Lantibiotic ECC

On September 22, 2021, the Company and Eleszto Genetika, Inc. mutually terminated the amended and restated worldwide exclusive channel collaboration agreement dated March 1, 2021 (the "Lantibiotic ECC") pursuant to which the Company was pursuing the development of OG716 as a lead product candidate for the treatment of *C. diff.*

As a result of the mutual termination of the Lantibiotic ECC, the Company will cease pre-clinical development of its product candidate OG716 and other compounds covered by the Lantibiotic ECC, all licenses provided pursuant to the Lantibiotic ECC between the parties were terminated and there are no continuing obligations between the parties, except as to confidentiality. The Company made no payments to EGI in connection with the mutual termination. Each party retained all right and title to their own respective intellectual property.

The Company will focus on its continuing independent research and development efforts relative to lantibiotics in order to identify new compounds to pursue.

Leases

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

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

	September 30, 2021	December 31, 2020
Weighted Average Remaining Lease Term In Years		
Operating leases	2.71	3.46
Weighted Average Discount Rate		
Operating leases	5.70%	5.70%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2021	$ 53,059
2022	217,379
2023	169,656
2024	146,719
Total	$ 586,813
Less: Imputed interest	(47,433)
Present value of lease liabilities	$ 539,380

The cost component of operating leases is as follows:

	For the Nine Months Ended September 30, 2021	For The Nine Months Ended September 30, 2020
Operating lease cost	$ 171,040	$ 169,126

Short-term lease cost	1,159	1,839
Total lease cost	$ 172,199	$ 170,965

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

	For the Nine Months Ended September 30, 2021	For The Nine Months Ended September 30, 2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 170,354	$ 169,264

9. Shareholders' Equity

Common Stock

During the nine months ended September 30, 2021, the Company issued756,540 shares of common stock in connection with the exercise of stock options which generated gross proceeds of $363,140.

During the three months ended March 31, 2021, the Company issued an aggregate of23,871,338 shares of common stock comprised of (i)21,398,765 shares of common stock issued in connection with sales of its common stock under its ATM 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.

The Company did not issue any shares of common stock pursuant to the ATM Program during the three months ended September 30, 2021

Preferred Stock

Series C Preferred Stock Dividend and Redemption

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

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

The following information should be read in conjunction with the Consolidated Financial Statements, including the notes thereto, included elsewhere in this Form 10-Q as well as our Annual Report on Form 10-K for the year ended December 31, 2020 filed on March 1, 2021.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are not historical facts, but are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. These forward-looking statements include statements about our strategies, objectives and our future achievement. To the extent statements in this Quarterly Report involve, without limitation, our expectations for growth, estimates of future revenue, our sources and uses of cash, our liquidity needs, our current or planned clinical trials or research and development activities, product development timelines, our future products, regulatory matters, expense, profits, cash flow balance sheet items or any other guidance on future periods, these statements are forward-looking statements. These statements are often, but not always, made through the use of word or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan," and "would. "These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may differ materially from those discussed in this Quarterly Report on Form 10-Q. Except as may be required by applicable law, we undertake no obligation to update any forward-looking statements or to reflect events or circumstances arising after the date of this Report. Important factors that could cause actual results to differ materially from those in these forward looking statements are in the section entitled "Risk Factors" in the most recent Annual Report on Form 10- K, as updated by our recent Form 8-K Report filed with the Securities and Exchange Commission, and the other risks and uncertainties described elsewhere in this report as well as other risks identified from time to time in our filings with the Securities and Exchange Commission, press releases and other communications. In addition, the statements contained throughout this Quarterly Report concerning future events or developments or our future activities, including concerning, among other matters, current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain sufficient funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring.

Overview

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

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

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 the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2"), which causes the coronavirus disease 2019 ("COVID-19"). Noachis Terra is a party to a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving pre-fusion stabilized coronavirus spike proteins and their use in the development and commercialization of a vaccine to provide specific, long lasting immunity from SARS-CoV-2.

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other body-systems, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2 (often referred to as COVID-19), which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). In October of 2021, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 245 million and the number of deaths directly attributed to COVID-19 have exceeded 5 million. Pfizer/-BioNTech received FDA approval for their COVID-19 vaccines in August of 2021 and the Moderna and Jansen vaccines are currently available in the United States under Emergency Use Authorizations by the FDA. We believe given the size of the worldwide pandemic that even with additional vaccines projected to be available in the months ahead, there will be demand for the Terra CoV-2 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license with our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health crisis. We believe our Terra CoV-2 vaccine holds the possibility of playing an important role in addressing this crisis.

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

The NIH's preclinical study shows that this spike protein, adjuvanted with the mouse specific TLR-4-agonist Sigma Adjuvant System ("SAS", a TLR-4 agonist) that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. Recently released information indicated that pretreatment of mice with the NIH-created COVID-19 spike protein in combination with the SAS adjuvant completely inhibited viral growth in the nasal cavities and lungs of infected animals compared to unvaccinated control animals. In October 2020, we received feedback to our Type B Pre-Investigational New Drug ("IND") Meeting Request from the FDA. The response indicated that the FDA broadly supported our planned approach to the pre-clinical program that will support the clinical development of the Terra CoV-2, vaccine.

We also anticipate that our Terra CoV-2 vaccine will provide long lasting protection from the SARS-CoV-2 virus including several variants with only one or two doses, with a more rapid immune response compared to vaccines developed without the inclusion of an adjuvant.

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

The Terra CoV-2 vaccine plus Biodextris' intranasal mucosal adjuvants are being and will be studied in the preclinical animal studies, including hamster viral challenge studies, mouse immunogenicity studies and the rodent toxicology study required for regulatory approval prior to the initiation human testing. We believe the Terra CoV-2 vaccine is expected to permit cost effective storage and distribution at refrigerated temperatures, which should facilitate the distribution and thereby avoid challenges facing the two mRNA vaccines currently available in the U.S.

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

We began preclinical studies in June of 2021 through our collaboration and material transfer agreement with the NRC. We initiated an immunogenicity study in mice to evaluate several adjuvant candidates. 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 2020 to assess inhibition of viral replication using adjuvants specific for intramuscular and intranasal administration, the completion of which is expected at the end of November 2021. Through assessment of a variety of factors including evolving variants and available vaccines in use, we have determined to focus our development efforts on the intranasal delivery of our vaccine product candidate. As a result we now expect to have another pre-IND meeting with the FDA and to file an IND application with the FDA in the second quarter of 2022 and immediately upon receipt of approval from the FDA to commence a Phase 1 clinical study, the protocol for which is currently under development.

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

Our Antibiotic Product Candidate-ODC-x

Members of our scientific team discovered that a certain bacterial strain.*Streptococcus mutans,* produces MU1140, a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram-positive bacterial species. Approximately 60 lantibiotics have been discovered, to date. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

In nonclinical testing, MU1140 has shown activity against all Gram-positive bacteria against which it has been tested, including those responsible for a number of healthcare associated infections, or HAIs. A high percentage of hospital-acquired infections are caused by highly antibiotic-resistant bacteria such as methicillin-resistant Staphylococcus aureus (MRSA) or multidrug-resistant Gram-negative bacteria. We believe the need for novel antibiotics is increasing as a result of the growing resistance of target pathogens to existing FDA approved antibiotics on the market along with the increased use of currently available antibiotics due to secondary infections in SARS-CoV-2 infected patients.

Lantibiotics have been difficult to investigate for their clinical usefulness as therapeutic agents in the treatment of infectious diseases due to a general inability to produce or synthesize sufficient quantities of pure amounts of these molecules. Traditional fermentation methods can only produce minute amounts of the lantibiotic.

In June 2012, we entered into a worldwide exclusive channel collaboration agreement with Precigen, Inc (formerly known as Intrexon Corporation), ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc. ("EGI"), for the development and commercialization of the native strain of MU1140 and related homologs to use its advanced transgene and cell engineering platforms.

In September of 2021, we and Eleszto Genetika, Inc., mutually terminated the amended and restated worldwide exclusive channel collaboration agreement dated March 1, 2021 (the "Lantibiotic ECC") pursuant to which we were pursuing the development of OG716 as a lead product candidate for the treatment of *C. diff.* As a result of the mutual

termination of the Lantibiotic ECC, we will cease pre-clinical development of our product candidate OG716 and other compounds covered by the Lantibiotic ECC, all licenses provided pursuant to the Lantibiotic ECC between the parties were terminated and there are no continuing obligations between the parties, except as to confidentiality. We made no payments to EGI in connection with the mutual termination. Each party retained all right and title to their own respective intellectual property. The termination of the Lantibiotic ECC was to enable us to focus on our continuing independent research and development efforts relative to lantibiotics in order to identify new compounds to pursue.

The timing of the filing of an IND regarding a 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.

We recently announced that 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 (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 vaccine product candidate. We hold a nonexclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine against SARS-CoV-2.

Additionally, we are developing various lantibiotic candidates while also creating semi-synthetic lantibiotic analogs that may be effective against systemic gram (+) multidrug infections, and analogs that may be effective in treating gram (-) infections. We seek to protect our product candidates through patents and patent applications pursuant to the terms of our license agreements.

Product/Candidate	Description	Application	Status
Terra CoV-2	Vaccine candidate (recombinant protein antigen + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
Antibiotics	A homolog of MU1140: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Pre-clinical testing

Our Business Development Strategy

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

Recent Developments

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

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

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

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

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

In forward with pre- 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 clinical testing.

Termination of the Lantibiotic Exclusive Channel Collaboration Agreement. On September 22 2021, the Company and Eleszto Genetika, Inc., mutually terminated the amended and restated worldwide exclusive channel collaboration agreement dated March 1, 2021 (the "Lantibiotic ECC") pursuant to which the Company was pursuing the development of OG716 as a lead product candidate for the treatment of *C. diff*. As a result of the mutual termination of the Lantibiotic ECC, the Company will cease pre-clinical development of its product candidate OG716 and other compounds covered by the Lantibiotic ECC, all licenses provided pursuant to the Lantibiotic ECC between the parties were terminated and there are no continuing obligations between the parties, except as to confidentiality. The Company made no payments to EGI in connection with the mutual termination. Each party retained all right and title to their own respective intellectual property. The termination of the Lantibiotic ECC was to enable Oragenics to focus on its continuing independent research and development efforts relative to lantibiotics in order to identify new compounds to pursue.

Received National Institute of General Medical Sciences Grant. We recently announced that the Company was 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 (Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter spp.).

Adjournment of Annual Shareholder Meeting. On June 30, 2021, the Company adjourned its annual meeting of shareholders due to lack of a quorum to conduct the annual meeting. The meeting was adjourned to attempt to achieve a quorum. On August 23, 2021, the Company adjourned its reconvened annual meeting of shareholder due to a lack of quorum to conduct the annual meeting. The Company has set a new annual meeting date of November 22, 2021, and a new record date of October 1, 2021.

Financial Overview

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

Our management has closely monitored the impact of COVID-19 on our business operations. Due to stay-at-home orders in the United States, we have instituted a work-from-home plan for our employees. We have no plans to furlough employees at this time. However, the Company is dependent on its workforce to deliver and advance its research. While expected to be temporary, prolonged workforce disruptions may negatively impact future operations in fiscal year 2021 and the Company's overall liquidity.

To date, we and our development partners, have been able to conduct ordinary operations at or near normal levels and do not currently anticipate any interruptions for the foreseeable future. However, there could be additional repercussions for our operations, particularly for the initial development of our Terra Cov2 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 assist with the conduct of our clinical trials and a substantial portion of our nonclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees, for and milestone payments related to, in-licensed products and technology; stock-based compensation expense; and costs associated with nonclinical activities and regulatory approvals. We expense research and development costs as incurred.

Our research and development expenses can be divided into (i) clinical research, and (ii) nonclinical research and development activities and (iii) manufacturing process development and analytical testing procedure development. Clinical research costs consist of clinical trials, manufacturing services, regulatory activities and related personnel costs, and other costs such as rent, utilities, depreciation and stock-based compensation. Nonclinical research and development costs consist of our research activities, nonclinical studies, related personnel costs and laboratory supplies, and other costs such as rent, utilities, depreciation and stock-based compensation and research expenses we incur associated with the development of our product candidates. While we are currently focused on advancing our product development programs, our future research and development expenses will depend on the nonclinical and clinical success of our product candidates, as well as ongoing assessments of each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans, research expenses and capital requirements.

Our research and development expenses were $9,275,800 and $18,755,013 for the nine months ended September 30, 2021 and 2020, respectively.

Our current product development strategy contemplates an expected increase in our research and development expenses in the future as we continue the advancement of our product development programs for our vaccine and lantibiotic product candidates, with greater near-term emphasis on our vaccine product candidate. The lengthy process of completing pre-clinical studies, clinical trials; seeking regulatory approval for our product candidates; and expanding the potential claims we are able to make, requires expenditure of substantial resources. Any failure or delay in completing pre-clinical studies, clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Our current product candidates are not expected to be commercially available until we are able to obtain regulatory approval from the FDA or the regulatory authority in other jurisdictions where we may seek approval.

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our NIH license and NRC license and our lantibiotic development 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 the development of our vaccine product candidate and as our financial resources permit. Our research and development projects are currently expected to be taken to the point where they can be licensed or partnered with larger

pharmaceutical companies.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, finance, and administrative functions. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, patent filing, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase for, among others, the following reasons:

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

Other Income (Expense)

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

Income Taxes

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

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

Results of Operations for the Three Months Ended September 30, 2021 and 2020

Research and Development. Research and development expenses were $3,547,321 for the three months ended September 30, 2021 compared to $3,498,361 for the three months ended September 30, 2020, an increase of $48,960 or 1.4%. This increase was primarily due to an increase in costs associated with the Terra CoV-2 vaccine program of $2,658,423. This increase was substantially offset by decreases in costs associated with our clinical trial work related to our oral mucositis product candidate, consideration relating to the acquisition of Noachis Terra, Inc., costs associated with our lantibiotic development program, salaries and stock-based compensation costs of $1,331,968, $1,220,780, $32,590, $28,121, and $7,637, respectively.

General and Administrative. General and administrative expenses were $847,134 for the three months ended September 30, 2021 compared to $1,010,006 for three months ended September 30, 2020, a decrease of $162,872 or 16.1%. This decrease was primarily due to decreases in salaries, filing and registration fees, non-employee stock-based compensation, and employee stock-based compensation costs of $104,152, $84,308, $68,889, and $17,659. This decrease was partially offset by increases in costs associated with board fees, and insurance costs of $58,667 and $41,024, respectively.

Other Income. Other income, net was $10,709 for the three months ended September 30, 2021 compared to $11,807 for the three months ended September 30, 2020, resulting in a net change of $1,098. The net change was primarily attributable to a decrease in interest income of $1,468 which was partially offset by an increase in interest expense of $3,167.

Results of Operations for the Nine Months Ended September 30, 2021 and 2020

Research and Development. Research and development expenses were $9,275,800 for the nine months ended September 30, 2021 compared to $18,755,013 for the nine months ended September 30, 2020, a decrease of $9,479,213 or 50.5%. This decrease was primarily due to decreases in costs associated with the acquisition of Noachis Terra, Inc., clinical trial work related to our oral mucositis product candidate under our ECC, contingent consideration payments, costs associated with our lantibiotic ECC, employee stock-based compensation, bonus costs, and salary of $9,955,699, $5,227,634, $678,527, $203,087, $75,797, $36,000, and $25,188, respectively. These decreases were partially offset by increases in costs associated with the TerraCoV2 vaccine program $6,782,738.

General and Administrative. General and administrative expenses were $4,194,103 for the nine months ended September 30, 2021 compared to $3,337,422 for nine months ended September 30, 2020, an increase of $856,681 or 25.7%. This increase was primarily due to increases in costs associated with non-employee stock-based compensation costs, board costs, insurance, filing and registration fees, and salary costs of $520,572, $172,875, $166,810, $151,621, and $75,026, respectively. This increase was partially offset by a decrease in employee stock-based compensation costs of $206,313.

Other Income. Other income, net was $50,865 for the nine months ended September 30, 2021 compared to $70,819 for the nine months ended September 30, 2020, resulting in a net change of $19,954. The net change was primarily attributable to a decrease in interest income of $15,255 and an increase in interest expense of $4,176.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public

offerings, and grants. During the nine months ended September 30, 2021and September 30, 2020 our operating activities used cash of $11,585,787, and $13,321,283, 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 $28,339,775 and $16,640,534 at September 30, 2021 and December 31, 2020, respectively.

During the nine months ended September 30, 2021 and September 30, 2020, our investing activities used cash of $24,123 and $-0-, respectively.

During the nine months ended September 30, 2021 and September 30, 2020, our financing activities provided cash of $23,919,227 and $5,096,902 respectively. The cash provided by financing activities during the nine months ended September 30, 2021 and September 30, 2020, was primarily due to the sales of common stock, the exercise of warrants, which were offset by the redemption of the Series C Preferred stock and payments on short term notes payable.

Financing

Additional details of our financing activities for the periods reflected in this report are provided below as well as certain information on our outstanding shares of preferred stock:

November 2020 Public Offering.

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

December 2020 Registered Direct Offering.

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

ATM Program

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

Other Financings

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

Products Liability Insurance

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

Directors' and Officers' Insurance

On July 24, 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 due on May 24, 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.

Preferred Stock – Series C Preferred Redemption and Outstanding

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

Our Outstanding Preferred Stock

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

Preferred Stock Series	Outstanding Shares	Common Stock Equivalents
Series A Preferred	9,417,000	941,701

Series B Preferred	6,600,000	1,320,002

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

Except as otherwise required by law, the Series A and Series B Preferred Stock have no voting rights. However, as long as any shares of Series A and series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A and Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A or Series B Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A and series B Preferred Stock, (c) increase the number of authorized shares of Series A and Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designations), the holders of Series A and Series B Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A and Series B Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A and Series B Preferred Stock if all outstanding shares of Series A and Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A and Series B Preferred Stock is classified as permanent equity.

Future Capital Requirements

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

Our current available cash and cash equivalents, provide us with limited liquidity. We believe our existing cash equivalents and cash will allow us to fund our operating plan into the third quarter of 2022. We expect to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts.

For example, as we seek to move forward with the development of Terra CoV2 vaccine candidate and our other product candidates, we will require additional capital. In addition, we continue to pursue other COVID-19 research and development funding opportunities through governmental and nongovernmental sources, as well as potential research collaboration arrangements with academic institutions and other commercial partners. Our ability to advance the development of our Terra CoV2 vaccine candidate at our anticipated pace, in accordance with our NIAID License and NRC License, will be dependent upon our ability to secure additional capital resources through these funding opportunities or an alternative capital raise, such as an equity or debt financing or other strategic business collaboration. Moreover, the global impact of COVID-19 could further impact our need for additional capital if we experience delays in our anticipated timelines or the achievement of milestones.

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

- conduct preclinical research for our Terra CoV-2 vaccine product candidate, file an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- our ability to advance our lantibiotic development;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures;
- 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;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amounts of sales of, or royalties on, our products and future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, grants, public or private sales of our shares or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The preparation of consolidated financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires

assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal areas of estimation reflected in the consolidated financial statements are stock-based compensation and valuation of warrants. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes to our critical accounting estimates during the three and nine months ended September 30, 2021.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three and nine months ended September 30, 2021 that have had or are expected to have an impact on our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Interim Principal Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Interim Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of September 30, 2021 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and exchange Commission's rules and forms.

Changes in Internal Controls over Financial Reporting

Our management, with the participation of our Interim Principal Executive Officer and Chief Financial Officer, has concluded there were no significant changes in our internal controls over financial reporting that occurred during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Interim Principal Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management or board override of the control.

The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed on March 1, 2021. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption "Risk Factors" in our Annual Report on Form 10-K.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and $13.4 million and $22.0 million for the nine months ended September 30, 2021 and September 30, 2020, respectively, and approximately $26.4 million and $15.6 million for the years ended December 31, 2020, and 2019, respectively. As of September 30, 2021, our accumulated deficit was approximately $169.0 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our plans to begin preclinical research, contract manufacturing and file an IND for our Terra CoV2 vaccine product candidate and the research and development of our product candidates in the area of lantibiotics will continue to increase the level of our overall expenses significantly going forward. Additionally, our NAIAD and NRC licenses 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 September 30, 2021, will be sufficient to fund our operations as presently structured into the third quarter of 2022. Our actual costs may ultimately vary from our current expectations, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations. Accordingly, we will need to seek additional sources of financing and such additional financing may not be available on favorable terms, if at all. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate or government collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, and research and development activities. Specifically, we need to raise additional capital to, among other things:

- conduct preclinical research for our Terra CoV2 vaccine product candidate, file an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- engage in GMP and non-GMP manufacturing for our product candidates at the preclinical research and clinical trial stages;
- expand our clinical laboratory operations and conduct further research and development on lantibiotics;
- fund our clinical validation study activities;
- expand our research and development activities; and
- finance our capital expenditures and general and administrative expenses.

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

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

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

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

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

The listing of our common stock on the NYSE American is contingent on our compliance with the NYSE American conditions for continued listing. One of the requirements for continued listing on the NYSE American, is the requirement that each issuer listing common stock or voting preferred stock, and/or their equivalents, to hold an annual meeting of shareholders no later than one year after the end of the issuer's fiscal year. The Company's annual meeting of shareholders, scheduled for June 30, 2021, at 9:00 a.m. was convened and adjourned, without any business being conducted, due to lack of the required quorum. On August 23, 2021, the Company adjourned its reconvened annual meeting of shareholder due to a lack of quorum to conduct the annua meeting. The Company has set a new annual meeting date of November 22, 2021, and a new record date of October 1, 2021.

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

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to the Amended and Restated Articles of Incorporation of Oragenics, Inc. Certificate of Designation and Rights of Series D Convertible Preferred Stock	8-K	001-32188	3.1	7/17/18	
3.5	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.6	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.7	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
10.0	National Research Council Canada Technology License Agreement (dated July 26, 2021) and Amendment One (dated September 2, 2021)*					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	XBRL Taxonomy Extension Label Linkbase					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase					X

* Confidential treatment has been asserted 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 19344, as amended.

EXHIBIT INDEX

* Non-material schedules and exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish supplemental copies of any of the omitted schedules and exhibits upon request by the SEC.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 15th day of November, 2021.

ORAGENICS, INC.

BY: /s/ Michael Sullivan
Interim Principal Executive Officer

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

[***] PORTIONS OF THIS EXHIBIT HAVE BEEN REDACTED PURSUANT TO ITEM 601(B)(2) OF REGULATIONS S-K AS (I) NOT MATERIAL AND (II) LIKELY TO CAUSE COMPETITIVE HARM IF PUBLICLY DISCLOSED. THE COMPANY HEREBY UNDERTAKES TO FURNISH UNREDACTED COPIES OF THIS EXHIBIT UPON REQUEST BY THE SECURITIES AND EXCHANGE COMMISSION; PROVIDED, HOWEVER, THAT THE COMPANY MAY REQUEST CONFIDENTIAL TREATMENT PURSUANT TO RULE 24B-2 OF THE EXCHANGE ACT FOR SUCH UNREDACTED COPIES OF THIS EXHIBIT.

THIS TECHNOLOGY LICENCE AGREEMENT ("Agreement") is made

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) office located at:
6100 Royalmount Avenue
Montreal, Quebec, H4P 2R2 Canada

Scientific Contact: Yves Durocher
E-mail: Yves.Durocher@nrc-cnrc.gc.ca
Business Contact: Alexandre Serrano
E-mail: alexandre.serrano@cnrc-nrc.gc.ca

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

a corporation under the laws of
the State of Florida

whose address is:

4902 Eisenhower Boulevard – Suite 125
Tampa, Florida 33634, U.S.A.

Scientific **Contact:** Martin Handfield

Email: mhandfield@oragenics.com
Business **Contact: Michael Sullivan**
Email: msullivan@oragenics.com

(NRC and Licensee may be referred to individually as a '**Party**" and collectively as the "**Parties**")

WHEREAS the NRC owns or controls certain technology as defined herein; and

WHEREAS the Licensee and its team are recognized for their experience in the development of innovative biopharmaceuticals; and

WHEREAS the NRC has signed a material transfer agreement with the Service Provider (as defined herein) for the tech transfer of the NRC Technology (as defined herein) to accelerate access to clinical material; and

WHEREAS the Licensee holds a license from the National Institute of Health for complementary technology that if combined with the NRC Technology will enable the Licensee to develop and commercialize vaccines targeting SARS-CoV2 and variants of concern;

WHEREAS the NRC and the Licensee desire to enter into a licence agreement that will permit the NRC Technology to be used for internal R&D and commercial purposes by the Licensee. **IN CONSIDERATION** of the following terms, conditions, promises, and payments, the Parties agree as follows:

1. DEFINITIONS IN THIS AGREEMENT

For all purposes of this Agreement the following terms, in singular or plural form as appropriate to the context, are defined as follows:

1.1 **"Affiliate**" shall mean any person or entity which, now or hereafter, directly or indirectly, controls, is controlled by, or is under common control with the Licensee; and for such purpose the term "control" shall mean the legal power to direct or cause the direction of the general management or business affairs of the Licensee whether through the ownership of more than fifty percent (50%) of the voting interest, by contract or otherwise. For clarity, Licensee's Affiliates are limited only to the list of organisations specified in Annex C provided that they meet the criteria of Affiliates mentioned herein above or any additions or modifications to the list approved in writing by the NRC.

National Research Council Canada | Conseil national de recherches Canada

Technology Licence Agreement
Exclusive/Sole ☐ - Non-Exclusive ☒
Business Confidential – Protected B

1.2 "**Agreement**" means this Technology License Agreement and all appendices and schedules thereto.

1.3 **"Arm's Length"** has the meaning as used for purposes of the *Income Tax Act* of Canada.

1.4 **"Contractors"** means contract manufacturing organizations ("**CMOs**"), contract research organisation ("**CROs**") to be used by the Licensee to perform research and/or manufacturing services on behalf of the Licensee. For clarity, the Contractors shall be limited only to facilities located in Canada and/or Contractors listed in Annex B of this Agreement unless otherwise agreed upon in writing by the NRC, provided that such approval shall not be unreasonably withheld. The Licensee shall consider first engaging Contractor facilities located in Canada before engaging with Contractor facilities not located in Canada and the Licensee shall provide the NRC with sufficient justification in writing for engaging Contractor facilities not located in Canada. Sufficient justification means that Contractor facilities located in Canada do not exist with the required technical capability, resourcing, facilities, infrastructure, and competitive pricing to meet Licensee's production needs, business needs, and timelines to make Drug Substance or Product without any undue delay .The Licensee shall enter into agreements with each Contractor including terms not less strict than the terms of this Agreement. In case of any breach by a Contractor, the Licensee shall notify the NRC with full details related to this breach within a maximum of 3 business days from the date the Licensee becomes aware of this breach. The Licensee shall act in good faith and shall exert all reasonable efforts to cure the breach after consulting the NRC.

1.5 "**Consultant**" means a third party expert assigned by the Licensee providing technical, business or legal advice and consultancy to the Licensee as per a contractual obligation with the Licensee.

1.6 "**Principal Investigator**" means a third party investigator assigned by the Licensee to lead clinical trials or other testing related to the Product as per a contractual obligation with the Licensee.

1.7 "**Develop**" means non-clinical drug development activities pertaining to a pharmaceutical product, including toxicology, pharmacology, test method development and stability testing, process and manufacturing development, formulation development, delivery system development, quality assurance and quality control development, and statistical analysis.

1.8 **"Due Diligence"** means the review process and business checks conducted by the NRC to ensure that no technology misuse, credit or business concerns exist in respect to any potential sub-licensee that could negatively impact the NRC's Technology.

1.9 **"Effective Date"** means the date the last Party has signed this Agreement.

1.10 "**First Commercial Sale**" means, with respect to a Product in a country in the Territory, the first arms-length commercial sale of such Product by the Licensee or a sub-licensee to a third party in such country after Regulatory Approval in such country. Sales for clinical study purposes, early access or compassionate use programs will not constitute a First Commercial Sale. In addition, sales of a Product by Licensee to its Affiliates and sub-licensees will not constitute a First Commercial Sale.

1.11 **"Government Purposes"** means research and development within the NRC by the NRC alone or in collaboration with a third party and the provision of services to the NRC's customers and manufacturing a Product or causing it to be manufactured for use by the NRC or in projects in which the NRC participates. The NRC retains rights for manufacturing the Drug Substance and the Product in government facilities or through third party contractors solely for Sale or distribution within Canada.

1.12 "**Know-How**" means any unpublished technical information, materials, and expertise, if any, owned by NRC that is necessary or useful to the practice of the Patents.

1.13 **"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, processes or methods for the production of Drug Substance.

1.14 **"CHO ^{2353} ™ Cell Line"** [***]

1.15 **"Stable Cells"** [***]

1.16 **"Additional Stable Cells"** [***]

1.17 **"License Confirmation"** means the written confirmation by the NRC authorizing the Service Provider to generate and transfer the Stable Cells to the Licensee.

1.18 "**Service Provider**" means Biodextris Inc., located at 525 Cartier West Boulevard, Laval, Québec, H7V 3S8, Canada, or any other organisation listed or to be listed in Annex Bapproved in writing by the NRC to generate Stable Cells on behalf of the NRC. Subject to the satisfaction of the NRC, for any additional Service Provider other than the Service Provider listed in Annex B, the Licensee shall provide to the NRC with a written request to engage additional Service Provider with sufficient justification for proposing the potential Service Provider ("**Service Provider Request**"). The NRC shall provide the Licensee with its written decision within thirty (30) days from the date of receipt of the Service Provider Request which will not be unreasonably withheld.

1.19 "**Service Agreement**" means the agreement signed or to be signed by and between the Licensee and the Service Provider to manage the production and transfer of the Stable Cells to the Licensee or Contractor, subject to providing the Service Provider with the License Confirmation.

1.20 **"Other Revenue"** means all payments, and the value of other consideration, which the Licensee is to receive in relation to sub-licenses, other than royalties from Sales of Product or Services by the sub-licensee. This includes, without limitation, initial fees, milestone payments, bonuses, periodic fees, fees for consulting, fees for upgrades, dividends, and the value of goods, services, equity and options to acquire equity.

1.21 **"Patents"** means the following patents and patent applications, plus any divisions, continuations, continuations-in-part, re-issues, re-examinations, supplemental protection certificates and extensions of any of the foregoing, plus any other NRC patents and patent applications in countries within the Territory, covering the NRC Technology or claiming priority of patenting rights from any other patent application within the Patents:

	NRC Ref.	Country	Appln no.	Patent no.	Status
2001-113 (11225) A Cumate-Inducible System for Regulated Expression in Mammalian Cells	2001-113-02	Belgium	2727088.3	1385946	Issued
	2001-113-03	Canada	2,446,110	2,446,110	Issued
	2001-113-04	Switzerland	2727088.3	1385946	Issued
	2001-113-05	Germany	2727088.3	1385946	Issued
	2001-113-07	France	2727088.3	1385946	Issued
	2001-113-08	United Kingdom	2727088.3	1385946	Issued
	2001-113-09	Ireland	2727088.3	1385946	Issued
	2001-113-10	Italy	2727088.3	1385946	Issued

	2001-113-12	United States	12/769,048	8,163,894	Issued
	2001-113-13	United States	10/135,362	7,745,592	Issued

2005-066 (11648) Development of a Reverse Cumate Transactivator (rcTA): Application for Protein Production in CHO Cells	2005-066-02	Canada	2,580,515	2,580,515	Issued
	2005-066-05	Singapore	200701811-2	130667	Issued
	2005-066-06	United States	13/070,975	8,252,556	Issued
	2005-066-07	United States	11/575,621	8,728,759	Issued
	2005-066-08	United States	12/331,786	7,935,788	Issued
	2005-066-09	France	5791567	1 797 186	Issued
	2005-066-10	United Kingdom	5791567	1 797 186	Issued
	2005-066-11	Netherlands	5791567	1 797 186	Issued
	2005-066-12	Switzerland	5791567	1 797 186	Issued
	2005-066-13	Germany	60 2005 049 431.6	1 797 186	Issued
	2005-066-14	Ireland	5791567	1 797 186	Issued
	2005-066-15	Belgium	5791567	1 797 186	Issued
	2005-066-16	Italy	502016000087019	1 797 186	Issued
2010-139 (12273) Genomic sequence for enhanced expression level and stability (SMAR System)	2010-139-02	South Korea	10-2013-7029053	10-1993938	Issued
	2010-139-03	Canada	2,832,922	2,832,922	Issued
	2010-139-04	China	2012800291909	2012800291909	Issued
	2010-139-07	Singapore	201307624-5	194473	Issued
	2010-139-08	United States	14/110,944	9,085,627	Issued
	2010-139-09	Switzerland	12771313.9	2697375	Issued
	2010-139-10	Germany	12771313.9	2697375	Issued
	2010-139-11	Denmark	12771313.9	2697375	Issued
	2010-139-12	France	12771313.9	2697375	Issued
	2010-139-13	United Kingdom	12771313.9	2697375	Issued
	2010-139-14	Ireland	12771313.9	2697375	Issued
	2010-139-15	Belgium	12771313.9	2697375	Issued
	2010-139-16	Netherlands	12771313.9	2697375	Issued
	2010-139-17	Sweden	12771313.9	2697375	Issued
2018-077 Epstein Barr Virus Origin of Replication to Increase Protein Productivity from CHO Cells	[***]	PCT	[***]		Pending
2014-095 (112671) CHO-BRI Cell Line for Biologics Production	No protection. Secret				

2021-008-01 Use of Human Resistin as a Trimerization Partner for Expression of Trimeric Proteins	[***]	United States	[***]		Provisional

[***]

1.22 **"NRC Intellectual Property Rights"** means Patents, copyright and other exclusionary rights as it relates specifically to the NRC Technology, and rights in respect of confidential information included in the NRC Technology.

1.23 **"Product"** means a final formulation of Drug Substance(s) and any other components, regardless of presentation, developed and manufactured by or on behalf of the Licensee. For clarity, all presentations containing identical Drug Substance(s) would be considered the same Product.

1.24 **"Drug Substance"** means only SARS CoV-2 spike protein manufactured by a Stable Cell

1.25 "**Regulatory Approval**" means :

(a) clinical studies for obtaining regulatory approval of the Product in a certain jurisdiction (including pre-and post-approval studies), regulatory affairs, pharmacovigilance, clinical study regulatory activities (including regulatory activities directed to obtaining pricing and reimbursement approvals); and

(b) all approvals (including any applicable governmental price and reimbursement approvals), licenses, registrations, and authorizations of any federal, national, multinational, state, provincial or local regulatory authority, department, bureau and other governmental entity that are necessary and sufficient for the marketing and sale of a product in a country or group of countries.

1.26 **"Reporting Date"** is the date in every year up to which royalties since the last Reporting Date are calculated as follows: *the anniversary of the Effective Date and each year thereafter*.

1.27 **"Service"** means any service to third parties that is provided by using any part of the NRC Technology (including all modifications made by the Licensee or the NRC), or by using a Product, or that relates to a Product, including (without limiting the generality of the foregoing) customization, maintenance, installation, training, consulting, testing, operating, dissemination of advertising or publicity, production, packaging and distribution.

1.28 **"Sale"** means any disposition of a Product, including renting, leasing, licensing, lending and bartering of a Product. It also means any instance of providing Service. It is considered to occur when a Product or Service is delivered or an invoice is issued, whichever occurs first. A Sale exists irrespective of the collection of any debt (regardless of any accounting principle), but not if money received is refunded. **"Sales", "Sell"** and **"Sold"** have corresponding meanings.

1.29 **"Sales Revenue"** means the gross price billed by the Licensee or sub-licensee on account of every Sale of a Product or Service less the following deductions:

(a) rebates granted and taken, except rebates granted wholly or partially in consideration of a third party's agreement to purchase anything that is not a Product or Service as defined in this Agreement;
(b) trade, promotional, or bulk-purchase discounts, not exceeding amounts that are customary in the trade;
(c) amounts repaid or credited by reason of rejections or returns of Products;
(d) custom duties, excise taxes, sales taxes, value-added taxes, if separately stated and charged on an invoice; and
(e) actual shipping and insurance costs in transporting Products to third parties if separately stated and charged on an invoice.

If Products or Services are bartered or gifted, or are disposed of through a transaction that is not at Arm's Length, the Sales Revenue shall be calculated as above, using the average of the gross price billed by the Licensee in recent Sales of equivalent Products or Services, and if there are no such Sales, then it shall be deemed to be the fair market value.

If a Product is incorporated as part of another article, the Licensee shall price the product separately on an invoice. When a distinct price for a Product is not invoiced, or when the price stated is not a reasonable price, the Sales Revenue shall be calculated as above, using the average of gross price billed by the Licensee in recent Sales of equivalent Products, and if there are no such Sales, then the Sales Revenue for the Product shall be deemed to be the gross price billed for the Sale of the article multiplied by the ratio of the manufacturing cost of the Product to the manufacturing cost of the article. The Licensee shall be responsible for providing satisfactory evidence of manufacturing costs. This paragraph does not apply to Services.

1.30 **"Territory"** means *Canada, Australia, UK, USA and European Union.*

1.31 [***]

1.32 "**Canadian Registration**" means the obligation on the Licensee to file for Regulatory Approval of the Product in Canada simultaneous or before filing for Regulatory Approval in any other country.

1.33 [***]

1.34 "**Canadian Vaccine Supply**" means the Canadian government commercial supply needs of Drug Substance and/or Product, as confirmed in writing by the relevant federal or provincial Canadian governments, within the Field of Use.

1.35 "**Field of Use**" means the definition stated in Section 2.2 of this Agreement.

2. LICENCE

2.1 **Grant:** The NRC grants to the Licensee a worldwide non-exclusive license of the NRC's Technology within the Field of Use subject to the following:

(a) to use the Stable Cells to make, research, or Develop Drug Substance within the Territory; and
(b) to file Regulatory Approval, export and Sell Product worldwide, subject to the satisfaction of the Canadian Registration requirements, [***]; and
(c) to engage Contractors within the Territory to use the Stable Cells to reproduce or make Drug Substance or Product on behalf of the Licensee to be used or Sold only by the Licensee. The Licensee may request in writing to engage contractors other than the Contractors listed in Annex B (the "**Contractor Request**") subject to the terms stated herein. The NRC shall, within thirty (30) days from the date of receipt of the Contractor Request, provide the Licensee with its written decision, which will not be unreasonably withheld. The Licensee agrees to consider the NRC's biomanufacturing capabilities for the production of the Drug Substance and/or the Product subject to the then agreed upon terms and conditions. For clarity, the Licensee shall always be liable for any breach by a Contractor as if it was a breach by the Licensee except for the case where the NRC is acting as a Contractor for the Licensee as per stated in Section 2.1(c) and (d) of this Agreement.

(d) upon receiving the written confirmation of the Canadian Vaccine Supply from the Canadian federal and/or provincial governments:

(i) Production in a Canadian facility:

In the event the Licensee decides to manufacture the Drug Substance and/or Product in a facility located in Canada, the Licensee shall provide a written notice to the NRC containing all information related to the production of the Drug Substance and/or Product to ensure the Licensee's compliance [***].

[***]

Exclusions: This license grant does not allow Licensee to genetically modify the NRC Technology for any reason whatsoever, or to use and exploit commercially such modified NRC Technology. This license grant does not include any right of Licensee to offer to sell or sell any of the NRC Technology in the form that it was delivered to Licensee by the NRC.

2.2 **Field of Use:** The Licensee shall not deal in any manner with the NRC Technology except as authorized under this Agreement for applications within the Territory and within the authorized field of use, which is: protein subunit vaccines against diseases caused by SARS CoV-2 and variants for sales worldwide.

2.3 **Exclusivity:** The rights granted to the Licensee by way of the licence under Section 2.1 of this Agreement are non-exclusive.

2.4. **Sub-licensing**: The Licensee may request in writing to sub-license the rights granted by this Agreement to a third party subject to the terms stated herein and obtaining the prior written consent of the NRC (the "**Sublicense Request**"), provided that such approval shall not be unreasonably withheld. The NRC, upon completion of a satisfactory Due Diligence on the sub-licensee, shall provide the Licensee with the NRC's written decision within thirty (30) days from the date of receipt of the Sublicense Request. Any sub-license approved by the NRC shall be subject to the fees payment stated in Section 3.5 of this Agreement. The Licensee may sub-license the rights granted by this Agreement to a third party who has entered into an agreement with Licensee to commercialize a Product, provided that:

(a) a copy of the sub-licence shall be submitted to the NRC as soon as it comes into effect;

(b) each such sub-licence shall end upon termination of this Agreement;

(c) each such sub-licence shall not permit further sub-licensing by the sub-licensee;

(d) each such sub-licence shall include terms at least as restrictive as those found in this Agreement including all applicable paragraphs in this Agreement, including, but not limited to, all the terms and conditions in Section 3 of this Agreement; and

(e) the Licensee hereby agrees that the NRC is entitled to treat any breach by a sub-licensee of its obligations under the sub-licence as a breach of this Agreement by the Licensee, and

(f) Licensee is responsible for collecting from any sub-licensee any fees and royalties payable under Section 3 of this Agreement and submitting them to the NRC. All other revenue collected by Licensee from sub-licensee is subject to payments as Other Revenue owed to NRC under Section 3.

Exclusions: Licensee does not have the right to sub-license to any third party the use of the Stable Cells, NRC Technology, the CHO$^{2353\ TM}$ Cell Line, or any of its components for expressing products other than the Product referred to in the sub-license to that third party.

2.5 **Canadian Content:** The Licensee shall make diligent efforts to produce Products in Canada, to maximize the use of Canadian-made materials in Products to the extent they are reasonably available, to conduct clinical trials for the Product in Canada and to obtain Regulatory Approval of the Product in Canada. Canadian-based sub-licensees shall be subject to the same requirements. Foreign-based sub-licensees are not so restricted.

2.6 **Delivery:**

2.6.1 Within thirty (30) days from receipt of the License Fee, the NRC shall give the Licensee:

(a) The License Confirmation for the Stable Cells listed in Annex A;

(b) a copy of NRC's relevant Patents, including the latest draft of any applications that have not matured into patents;

(c) a copy of documentation that is reasonably necessary for an understanding of the NRC Technology, to the extent that it exists, for clarity this shall include supportive documentation related to the CHO2353 ^{TM} Cell Line only to the extent needed for the purpose of obtaining Regulatory Approval of a Product; and

(d) unless previously delivered, the NRC shall provide the current or future approved Service Provider with the protocols, documents and materials needed for the generation of Stable Cells listed in Annex A. For clarity, these materials shall only be provided to the Service Provider.

2.6.2 For any Additional Stable Cells to be listed to Annex A of this Agreement,

(a) the Licensee shall send a written request to the NRC to list Additional Stable Cells in Annex A of this Agreement.

(b) Upon the NRC's written approval, the Licensee shall provide the NRC with the payment stated in Section 3.2 (a) of this Agreement.

(c) The NRC will provide the Licensee with the License Confirmation for the Additional Stable Cells within thirty (30) days from the receipt of the fees stated in Section 3.2 (a) of this Agreement.

(d) The NRC will provide the current or future approved Service Provider with the needed protocols, documents and materials for the generation of the Additional Stable Cells.

The Licensee shall be conclusively deemed to have received all necessary delivery under this paragraph if the Licensee has not notified the NRC, within sixty (60) days from the shipment date stated in the shipping invoice, that delivery is lacking.

3. **FEES AND ROYALTIES**

3.1 **Licence Fee:** As consideration for the grant of the licence, within thirty (30) days of receiving a fully signed original of this Agreement the Licensee shall pay the NRC the sum of forty thousand US dollars (USD $40,000) for a three (3) year licence. Yearly renewal fee payable on the third anniversary of the Effective Date and annually thereafter: fifteen US dollars (USD $15,000) per year until First Regulatory Approval.

3.2 **Milestone Payments**: The following amounts shall be paid to the NRC within thirty (30) days after the occurrence of each milestone:

(a) [***] payment for each Stable Cell listed in Annex A of this Agreement and for each Additional Stable Cell that may be listed in Annex A as per stated in Section 2.6.2 of this Agreement; and

(b) Milestones Payments per Product:

	Product achievement of milestones			
3.3 Milestone (Each milestone shall be payable once per Product)	**First achievement of a milestone by a Product (USD$)**	**Second achievement of a milestone by a Product (USD$)**	**Third achievement of a milestone by a Product (USD$)**	**Subsequent achievements of a milestone by a Product (USD$)**
1- Submission of INDs	[***]	[***]	[***]	[***]
2- Dosing the first patient in a phase 1/2 clinical trial	[***]	[***]	[***]	[***]
3- Dosing the first patient in a phase 3 clinical trial	[***]	[***]	[***]	[***]
4- First Regulatory Approval	[***]	[***]	[***]	[***]

3.4 **Milestone Payment Reductions**: The Licensee's Milestone Payments due to the NRC shall be reduced in the following situations:

(a) Milestone Payments will be reduced by [***] for milestones achieved with Drug Substance that Licensee or its Contractors manufactures in Canada; or

(b) Milestone Payments will be reduced by [***] for milestones achieved with Product that Licensee or its Contractors manufactures in Canada.

For clarity, nothing in this section could be interpreted as granting the Licensee a reduction combining the reductions stated in (a) and (b) of this Section 3.3.

3.5 **Licensee's Royalty:** The Licensee shall pay to the NRC [***] of Sales Revenue as royalties for all Sales of Products from the Reporting Date following the First Commercial Sale and on each Reporting Date thereafter.

3.6 **Royalty Reductions**: The Licensee's Royalty due to the NRC shall be reduced in the following situations:

(a) Canadian Government supply: Subject to providing any Canadian Federal or Provincial governmental bodies or non-profit organizations the Product at a reduced price accepted by the respective authority, the Royalty Rate on such Sales of Final Products will be waived.

(b) Humanitarian use: Subject to providing sufficient evidence to the NRC that the Licensee provided the humanitarian organization Final Products without any profit margin, the Royalty Rate on such Sales of Final Products will be reduced by 100%.

3.7 **Sublicense Fee**: The Licensee shall pay to the NRC a Sublicense fee of USD [***] upon signature of each Sublicense.

3.8 **Payment Due Dates:** Payments due under Section 3 of this Agreement are due sixty (60) days after the Reporting Date. NRC does not need to invoice these amounts for these amounts to be due, but NRC will issue receipts. Payments must be accompanied by a Statement whose content is specified in Section 3.12.

3.9 **Tax:** The Goods and Service Tax, or Harmonized Sales Tax, or Quebec Sales Tax, is applicable to all payments required by this Agreement, depending on the residence of the Licensee or sub-licensee, while none of those taxes normally applies to foreign-based payers. It is the responsibility of the payer, whether Licensee or sub-licensee, to determine tax status and to pay to the NRC the applicable tax in addition to the payments required by this Agreement. The NRC's GST and HST registration number is [***]. The NRC's QST registration number is [***].

3.10 **Withholding Tax**: In the event that all or part of the payments payable by Licensee to the NRC are subject to a withholding tax in the country of sale, the Licensee shall increase the amount of such payments so that the net payments to the NRC correspond with amounts set out in this Agreement.

3.11 **Interest and Administrative Charges:** Interest is payable on all overdue amounts. Interest on overdue amounts is calculated and compounded monthly at the average bank rate plus 3% and accrues during the period beginning on the due date and ending on the day before the day on which payment is received by the NRC. For purposes of this paragraph "**bank rate**" means the rate of interest established periodically by the Bank of Canada as the minimum rate at which the Bank of Canada makes short term advances to members of the Canadian Payments Association, and "**average bank rate**" means the weighted arithmetic average of the bank rates that are established during the month before the month in respect of which interest is being calculated. Where an instrument tendered in payment or settlement of an amount due to the NRC is, for any reason, dishonoured, an administrative charge of $25 is payable to the NRC and is due as invoiced.

3.12 **Delinquent Accounts:** The NRC may use a collection agency to collect any debt arising under this Agreement, and the NRC may obtain a set-off of the debt against any other money payable by the Government of Canada to the Licensee. The costs and fees of collection agencies shall be added to the debt payable to the NRC.

3.13 **Statements:** The Licensee must deliver royalty statements to the NRC within sixty (60) days after each Reporting Date, even if no Products or Services were Sold. The NRC may provide a form for royalty statements, which the Licensees must use. Royalty statements must be certified accurate and correct by the Chief Financial Officer or some other senior officer of the Licensee, and must include the following information for the period up to the Reporting Date or since the last Reporting Date:

(a) the quantity of Products made by or for the Licensee;
(b) the quantity, and the Sales Revenue, for Products Sold at Arm's Length;
(c) the quantity of Products disposed of at other than Arm's Length or by barter, the persons to whom disposed, and the basis for the royalties;
(d) Sales Revenue from Services Sold;
(e) the nature of Other Revenue received and its value;
(f) a calculation of the royalties due to the NRC;
(g) projection of Sales of Products and Services for the periods to be covered in the next two royalty statements; and
(h) where applicable, identical information as in (a) to (g) from the sub-licensees certified as accurate and correct by the Chief Financial Officer or some other senior officer of the sub-licensee.

3.14 **Remittances:** Royalty statements must be accompanied by a remittance of the royalties due, in Canadian or U.S. funds payable at par at Ottawa, Ontario, Canada. Remittances can be made either by a bank transfer to an account which the NRC will designate if asked, or by a cheque payable to: "Receiver General – National Research Council", indicating on the cheque the reference number (if any) appearing on the first page of this Agreement. Cheques must be addressed to:

Accounts Receivable, at the head office address stated above on page 1.

A copy of the royalty statement must also be sent to:

(a) Intellectual Property Services, at the head-office address stated on page 1; and

(b) The *Human Health Therapeutics* Research Centre Business Office, at the head office stated on page 1.

3.15 **Currency Translation:** Sales Revenue and Other Revenue, and any fixed payment to the NRC required by this Agreement, when required to be converted to Canadian dollars, shall be converted using the Bank of Canada monthly exchange rate for the last month of the reporting period. This currency information is available at the Bank of Canada website: http://bank-banque-canada.ca/english/xrate.htm. If payments to the NRC are required to be made in U.S. dollars, the conversion shall be the rate of exchange in a major financial market, as published (errors excluded) in a widely distributed Canadian or U.S. newspaper on the last date of the reporting period, or within the seven preceding days. The basis of all conversions shall be stated in the royalty statement submitted to the NRC, accompanied by a printed copy of the published basis of that conversion.

3.16 **Records**: The Licensee shall, and shall require sub-licensees to:

(a) keep accurate, detailed and complete records in accordance with generally accepted accounting principles, at its expense, which shall be retained and available at its principal place of business in respect of Products and Services, and the basis of any Other Revenue which may require a payment to the NRC;
(b) provide the NRC, upon request and without charge, with annual financial statements (prepared by an external auditor, if available); and
(c) keep all the records intact for a period of not less than three (3) years.

3.17 **NRC's Audits:** The Licensee shall make all relevant records relating to payments required under this Agreement available at its premises during normal business hours, upon reasonable notice, and permit the NRC and its authorized representatives to audit, inspect, and copy the records. In such circumstances, the Licensee shall afford all facilities and collaboration to the NRC and its authorized representatives, and furnish all information necessary to the understanding of the records. If the NRC's audit reveals that payments made by the Licensee are less than nine-tenths (90%) of the amount that should have been paid, the Licensee shall reimburse the NRC's cost of the audit which becomes a debt due immediately to the NRC, along with the shortfall in royalties and Other Revenue with interest from the date on which the payments should have been made. If the Licensee presents obstacles to the audit, such that a Chartered Accountant makes an affidavit that the audit is impossible or impractical, the Licensee shall be deemed by this clause to have agreed that the NRC may estimate a fair value of the royalties and share of Other Revenue payable, based on the best information available, and the Licensee shall pay that amount to the NRC immediately together with interest from the date on which the payments should have been made, and shall reimburse the NRC's costs of the attempted audit.

3.18 **Licensee's Audits:** The Licensee shall give reasonable advance notice to the NRC of the scheduling of the Licensee's audits. At its option, the NRC shall be entitled to an audit of all relevant records relating to payments required under this Agreement, including all information necessary to the understanding of such records, as part of the Licensee's audit, at no cost to the NRC. When the NRC gives reasonable advance notice of requiring that audit, the Licensee will provide the NRC with an audited statement prepared by an external auditor that will verify such records in any year for which an audit has not been completed at the time the NRC gives notice. If the audit reveals a shortfall in what was paid to the NRC, the Licensee shall pay the shortfall amount to the NRC within sixty (60) days, with interest from the date on which the payments should have been made. If the audit reveals that payments made by the Licensee are not less than nine-tenths (90%) of the amount that should have been paid, the NRC shall reimburse the Licensee for any incremental costs of the additional part of the audit.

3.19 **Continuing Rights:** The rights granted in the preceding three (3) paragraphs shall survive the termination of this Agreement for a period of three (3) years.

3.20 **Allocation of Technology:** If requested, the Licensee shall cooperate with the NRC in providing information about a reasonable allocation of the Licensee's Sales Revenue and Other Revenue, and therefore of royalties, amongst the various elements of the Products or Services.

3.21 **Common Interest Privilege:** Attorney-Client Privilege. Subject to Section 6, neither Party is waiving, nor will be deemed to have waived or diminished, any of its attorney work product protections, attorney- client privileges or similar protections and privileges as a result of disclosing information pursuant to this Agreement, or any of its confidential information (including confidential information related to pending or threatened litigation) to the receiving Party, regardless of whether the disclosing Party has asserted, or is or may be entitled to assert, such privileges and protections. The Parties:

(a) share a common legal and commercial interest in such disclosure that is subject to such privileges and protections;
(b) may become joint defendants in proceedings to which the information covered by such protections and privileges relates;
(c) intend that such privileges and protections remain intact should either Party become subject to any actual or threatened proceeding to which the disclosing Party's confidential information covered by such protections and privileges relates; and
(d) intend that after the Effective Date both the receiving Party and the disclosing Party will have the right to assert such protections and privileges.

4. INTELLECTUAL PROPERTY

4.1 **Patenting Responsibility:** The NRC shall bear the responsibility and pay the costs to obtain and maintain Patents in the U.S., Canada, and EU (validation within individual European countries determined post-acceptance/allowance by the European Patent Office). The NRC shall use reasonable efforts to obtain and maintain those Patents. Additional national phase entry of provisional applications in other countries may be requested by the Licensee and shall be filed and maintained by the NRC provided the Parties negotiate in good faith the payment terms related to sharing expenses to any additional countries including, without limitation, the cost of obtaining and maintaining patent and the NRC's internal costs.

4.2 **Patenting Marking:** If the Licensee markets Products in the U.S. and a U.S. Patent applies, the Licensee shall, and shall require sub-licensees to, mark all Products with the Patent numbers so as to obtain the full benefit of U.S. law.

5. TECHNICAL ASSISTANCE

5.1 **Assistance Available:** The NRC shall supply the Licensee with technical assistance relating to the NRC Technology for up to one hundred and twenty (120) hours of time to be utilized within the first six (6) months of this Agreement. Incremental costs (such as overtime, travel, equipment fees), or any further time required, will be charged to the Licensee at standard NRC charge rates.

5.2 **Licensee's Improvements or Additions:** In the event that the Licensee produces additions or changes to the NRC Technology, which by their nature could not be used without some use of the NRC Technology, the Licensee shall provide the NRC, within ninety (90) days from the time of additions or changes have been made, with all available technical information concerning them, including source code if software is involved, and shall be deemed to license the NRC to use them for Government Purposes at no cost to the NRC.

5.3 **Grant Back:** The Licensee hereby grants to the NRC, and shall execute any documents reasonably required by the NRC as additional evidence of this, a non-exclusive, unconditional, irrevocable, perpetual, royalty-free licence, including the right to sub-license, to make, use or sell articles incorporating any additions and changes made by the Licensee which were required by the preceding paragraph to be reported to the NRC, whether patentable or unpatentable, without any obligation to account to the Licensee. The NRC retains rights for manufacturing the Drug Substance and the Product for Government Purposes only.

6. CONFIDENTIALITY

What is Confidential: The NRC Technology is confidential to the NRC except for published elements and elements which the NRC states in writing to be not confidential. In addition any documents of either Party marked "Confidential", "Protected", "Proprietary", or similar words, are confidential to that Party.

6.1 **Licensee's Obligations of Confidentiality:** Except to the extent expressly authorized in this Agreement, the Licensee shall protect the NRC Technology with the same degree of care as it uses to protect its own confidential information, but not less than a reasonable degree of care. The NRC Technology shall not be disclosed by the Licensee except:

(a) as required for a Contractor, Service Provider or a sub-licence to a third party including a prospective sub-licensee bound by a confidentiality obligation not less strict than the terms of confidentiality stated in this Agreement;
(b) if the NRC Technology has entered the public domain without breach of this Agreement;
(c) as required to be disclosed by law provided that the Licensee first provides the NRC with notice of such requirements and of its intent to disclose the information;
(d) as otherwise agreed to by Parties.

This clause shall survive the expiration or termination of this Agreement.

6.2 **NRC's Obligations of Confidentiality:** Unless otherwise stipulated in a separate agreement, the NRC shall, for a period of five (5) years after termination of this Agreement, maintain in confidence and protect the Licensee's confidential information with the same degree of care as it uses to protect its own confidential information, but not less than a reasonable degree of care, provided that these obligations do not apply to information that is:

(a) independently developed by the NRC without reference to or use of the Licensee's confidential information;
(b) received from a third party without breach of any obligation of confidentiality;
(c) in the public domain at the time of its disclosure or that later becomes publicly available without breach of this Agreement; or
(d) required to be disclosed by law, including in the case of the NRC, the *Access to Information Act* of Canada, provided that the NRC first provides the Licensee with notice of such requirements and of its intent to disclose the information.

Notwithstanding the foregoing, the NRC may disclose the particulars of this Agreement to others of its officers and employees for internal administrative and business purposes, to the extent that such disclosure does not result in a public release of Licensee's confidential information.

6.3 **If Confidentiality is Lost:** This Agreement remains in effect regardless of any loss of confidentiality of the NRC Technology at any time for any reason, although each party retains the right to terminate this Agreement for a breach by the other Party.

6.4 **Authorized Disclosure**. Notwithstanding the limitations in this Article 6, either Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

(a) complying with applicable laws or regulations or valid court orders, *provided that* the Party making such disclosure provides the other Party with reasonable prior written notice of such request or demand for disclosure and makes a reasonable effort to obtain, or to assist the other Party in obtaining, a protective order preventing or limiting the disclosure and/or requiring that the terms and conditions of this Agreement be used only for the purposes for which the law or regulation required, or for which the order was issued;

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(b) to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval, of Products, provided that the Party making such disclosure (i) provides the other Party with reasonable opportunity to review any such disclosure in advance and to suggest redactions or other means of limiting the disclosure of such other Party's Confidential Information and (ii) does not unreasonably reject any such suggestions;

(c) subject to Section 13.6 of this Agreement, disclosure to investors and potential investors, acquirers, or merger candidates who agree to maintain the confidentiality of such information, *provided that* such disclosure is used solely for the purpose of evaluating such investment, acquisition, or merger (as the case may be);

(d) disclosure on a need-to-know basis to Affiliates, sublicensees (subject to Section 2.4 of this Agreement), employees, Consultants, Principal Investigators and Contractors who agree to be bound by obligations of confidentiality and non-use not less strict than the terms of this Agreement .

7. DILIGENT EXPLOITATION

7.1 **Requiring Diligence:** The licence granted by this Agreement is conditional upon diligent exploitation of the rights granted to the Licensee, in a manner likely to satisfy the demand for the Products and Services in relation to all reasonable applications within the authorized field of use, and to adequately serve the Licensee's customers, throughout the world. If the NRC suspects a lack of diligence, the NRC will give written notice to the Licensee, inviting the Licensee to explain to the satisfaction of the NRC, in writing within six (6) months, why the level of exploitation should be considered satisfactory. Diligence will be judged without regard to royalties or minimum royalties paid. The NRC reserves the right to find a lack of diligence after the six-month notice and after having studied any response made by the Licensee, and this decision shall be conclusive, subject only to the dispute resolution provisions of this Agreement.

7.2 **Consequence of Lack of Diligence:** On a country-by-country basis, when the NRC finds a lack of diligence in accordance with the preceding paragraph, the NRC has the right to exercise one or more of the following recourses:

(a) convert any exclusivity to non-exclusivity;
(b) terminate the licence; or
(c) modify the field of use.

The NRC shall not exercise rights under this Article 7.2 before *the second anniversary of the Effective Date*, but the NRC's demand for justification can be made earlier.

7.3 **Multiple Occurrences:** The procedure for challenging diligence, and the consequences, may be invoked more than once.

8. USE OF THE NRC'S NAME

8.1 **Authorized Use**: The NRC hereby authorizes the Licensee, and the Licensee agrees to take all reasonable opportunities, such as in sales literature or press releases, to acknowledge the NRC as the source of the NRC Technology; but not so as to imply, in any such acknowledgement, that the NRC endorses or approves any Product or Service offered for Sale by the Licensee. Upon request, the Licensee shall provide the NRC with copies of the Licensee's written communications containing references to the NRC.

8.2 **Control of Use:** The NRC reserves the right, in its sole discretion, to control any unauthorized use of its name and may notify the Licensee that it must immediately cease any such use of the name, including any abbreviations, words, or images that imply an association with the NRC. Upon receipt of such notification, the Licensee must use its best efforts to withdraw from circulation any written material that represents an unauthorized use.

9. WARRANTIES, INDEMNITIES AND INSURANCE

9.1 **Representation and Warranty of Licensing Rights:** The NRC represents and warrants that it has not previously granted any rights that would conflict with the rights granted to the Licensee by this Agreement. The NRC also warrants that it is either the current owner or licensee (with power to sub-license) of the NRC Technology.

9.2 **No Implied Warranties:** Except for representations, warranties or conditions expressly made in this Agreement, the NRC Technology is supplied and licensed on a "as is" basis, and there are no representations, warranties or conditions, express or implied by statute, including without limitation any with respect to:

(a) market readiness, merchantability, or fitness for any use or purpose;
(b) compliance with regulatory requirements;
(c) operational state, character, quality, or freedom from defects;
(d) validity of Patents; and
(e) non-infringement of rights of third parties under present or future patents.

For clarity, it is the responsibility of the Licensee to undertake risk analysis related to the NRC Technology and its use.

9.3 **No Contestation of Validity:** The Licensee acknowledges the validity of the Patents and copyright, if any, licensed hereunder and agrees not to contest such validity during the life of this Agreement, either directly or indirectly by assisting other parties.

9.4 **Limited Damages:** The NRC shall not be liable, in any event, for consequential or incidental damages; or loss of income, arising from the possession or use of anything licensed or conveyed pursuant to this Agreement.

9.5 **Improper Conduct:** The Licensee represents and warrants:

(a) that the following individuals shall not derive a direct benefit from this Agreement:

(i) a current or former public office holder who is not in compliance with the *Conflict of Interest Act,*2006,c.9 s2;
(ii) a current or former Member of the House of Commons that is not in compliance with the Conflict of Interest Code for Members of the House of Commons;
(iii) a current or former public servant who is not in compliance with the Values and Ethics Code for the Public Sector; or
(iv) a current or former public servant who is not in compliance with the NRC's *Conflict of Interest Policy*;

(b) that its Directors, officers, employees or agents, has made no material misrepresentation, whether by omission or commission, with a view to influencing the entry into this Agreement or the administration of this Agreement;

(c) that no bribe, gift, reward, benefit or other inducement has been or will be paid, given, promised or offered directly or indirectly to any federal government official or employee or to any family member of such a person; and

(d) that it has not directly or indirectly paid or agreed to pay and that it will not directly or indirectly pay a contingency fee for the solicitation, negotiation or obtaining of this Agreement to any person, other than an employee acting in the normal course of the employee's duties, and for the purpose of this paragraph 9.5(d) a contingency fee means any payment or other compensation that depends or is calculated based on the degree of success in soliciting, negotiating or obtaining this Agreement and "person" includes any individual who is required to file a return with the registrar pursuant to the *Lobbying Act*, R.S.C.,1985,c.44 (4th Supplement) as amended.

9.6 **Indemnity:** The NRC rejects all liability and responsibility relating to the consequences of using the Products or providing Services. The Licensee shall indemnify and save harmless the NRC, its employees and agents from and against, and be responsible for:

(a) 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:

(i) the manufacturing, distribution, shipment, offering for Sale, Sale, or use of Products, Services or the NRC Technology; and product liability and infringement of intellectual property rights other than copyright, if any, licensed hereunder;

(b) other costs, including extra-judicial costs, of the NRC defending any such action or proceeding, which the NRC shall have the right to defend with counsel of its choice.

This clause shall survive expiration or termination of this Agreement.

9.7 **Insurance:** The Licensee shall procure and maintain, at its own expense, during the term of this Agreement commercial general liability insurance that includes product liability, which insurance shall name the NRC as an additional insured [***]. The minimum amount of insurance coverage required under this Agreement shall not be construed as a limit of liability. The Licensee shall provide to the NRC, within 30 days of execution of this Agreement, satisfactory evidence of such insurance, either in the form of a certificate or letter of insurance.

10. INFRINGEMENT LITIGATION

10.1 **Consultation:** If the Licensee receives or becomes aware of any claim or assertion by a third party that any activities by the Licensee under this Agreement constitute an infringement or other violation of a third party's patents or other intellectual property, the Licensee shall notify the NRC and shall provide the NRC with all details relating to the allegation. The Parties shall promptly enter into discussions with the third party to determine the extent and validity of the infringement and the Parties mutually agreed course of action. Each Party will absorb its own costs of the discussions.

10.2 **Negotiations:** The Parties may negotiate with a third party, to obtain any additional rights required, such as may arise if a third party's patent emerges. Each Party will absorb its own cost of negotiation. If those additional rights require payment, the Parties will negotiate for a reduction in royalties payable to the NRC, and failing agreement within sixty (60) days, either Party may invoke the arbitration procedure in this Agreement to settle the amount of the reduction of the royalty.

10.3 **Legal Action Commenced by the Licensee:** The Parties may agree to jointly defend or pursue litigation regarding infringement of any NRC Technology, but neither Party shall bind or commit the other Party to any course of action that involves liability for legal costs, expenses or damages. If the Parties fail to agree, within a reasonable time as to any course of action with might be jointly taken, the Licensee may commence proceedings alone, and if any amount is awarded to it by a court or paid to it as a settlement by the third party, the Licensee shall pay to the NRC royalties as specified in this Agreement on the amount of the judgment or settlement attributable to infringing sales, the excess of that amount over costs reasonably incurred by the Licensee for the litigation or settlement shall be treated as Sales Revenue of the Licensee for the purpose of calculating royalties. With respect to any amount of punitive damages awarded by the court or granted under a settlement, the Licensee shall pay to the NRC one-third thereof. If the Licensee proceeds alone in respect of such litigation, the NRC shall reasonably cooperate in any such litigation at the Licensee's expense.

10.4 **Legal Action Commenced by the NRC:** If the NRC commences proceedings alone, at its own expense, in respect of infringement of any NRC Intellectual Property Rights, the NRC shall be entitled to retain for its own account any amount of money recovered**.**

11. DURATION AND TERMINATION

11.1 **Expiration:** This Agreement shall become effective when it has been signed by both Parties. Unless terminated or extended earlier in writing by the Parties, this Agreement shall terminate on the **20th anniversary of the Effective Date**

11.2 **Termination by Either Party for Default or Breach:** In the event that one Party defaults or breaches any of the provisions of this Agreement, the other Party shall have the right to terminate this Agreement by giving written notice to the defaulting Party, but this act shall not prejudice the right of a Party to recover any fee due at the time of such termination and shall not prejudice any cause of action or claim of a Party accrued or to accrue on account of any breach or default by the other Party. However, if the defaulting Party cures the breach within sixty (60) days after the notice is given, this Agreement shall continue in full force and effect.

11.3 **Termination by the NRC:** This Agreement, at the option of the NRC, may be terminated forthwith by the NRC if the Licensee becomes bankrupt, or insolvent, or has a receiver appointed to continue its operations, or passes a resolution for winding up.

11.4 **Procedure on Termination:** Upon termination the Licensee shall:

(a) deliver a detailed statement to the NRC of the inventory of all Products then existing and not Sold by the Licensee as at that date;
(b) retain the right to Sell Products then existing and shall pay royalties to the NRC as Products are Sold for a period of one year provided that any remaining inventory of Products shall be destroyed by the Licensee at the end of that year and proof thereof provided to the NRC;
(c) retain the right to deliver Services for which a contractual commitment has been made before termination, for a period of one year, subject to the continued obligation to pay Royalties on the Sales Revenue for those Services; and
(d) cease any other use of the NRC Technology unless the NRC Technology, in total, has then become part of the public domain other than through any act or omission of the Licensee.

11.5 **Accrued Obligations:** Termination does not release a Party from any obligations, which accrued while in this Agreement was in force or upon its termination.

12. LAWS AND DISPUTES

12.1 **Choice of Law:** This Agreement shall be interpreted according to the laws of the Province of Ontario and the laws of Canada in force there.

12.2 **Court:** Subject to Article 12.3, for any litigation concerning this Agreement, including litigation arising from arbitration, the Parties hereby irrevocably and unconditionally attorn to the exclusive jurisdiction of the Courts of the Province of Ontario, and all courts competent to hear appeals therefrom. The Parties expressly exclude any conflict of laws rules or principles that might refer disputes under this Agreement to the laws of another jurisdiction. Despite the foregoing, if this Agreement or any aspect of it becomes a subject of judicial proceedings in the United States of America, then the Licensee irrevocably waives any and all rights it has to a trial by jury in the United States, and the Licensee agrees that the matter will be heard before a judge sitting alone, due to the nature and complexity of the NRC Technology and applicable laws.

12.3 **Dispute resolution**: Disputes concerning this Agreement shall not be litigated. All disputes arising in connection with this Agreement which cannot be resolved through negotiations to the mutual satisfaction of both Parties within thirty (30) days, or such longer period as may be mutually agreed upon, may be submitted by either Party to arbitration in accordance with the *Commercial Arbitration Act* of Canada, R.S.C., 1985, c. 17 (2nd Supp.), as amended, and shall be subject to the following:

(a) The Party requesting arbitration shall do so by written notice to the other Party.

(b) The arbitration shall take place in Ottawa, Ontario before a single arbitrator to be chosen jointly by the Parties. Failing agreement of the Parties on a single arbitrator within thirty (30) days of the notice requesting arbitration, either Party may apply to a judge of a court having jurisdiction in Ottawa, Ontario for the appointment of a single arbitrator.

(c) Each Party shall pay its own costs and an equal share of all of the costs of the arbitration and the fees of the arbitrator, except for the exceptional circumstance in which an arbitral award may require the payment of all costs by a Party who has brought a plainly frivolous dispute.

(d) The arbitrator shall issue a written decision as soon as practicable after the conclusion of the final hearing, but in any event no later than sixty (60) days thereafter, unless that time period is extended for a fixed period by the arbitrator on written notice to each Party because of illness or other cause beyond the arbitrator's control. The decision shall be in the form of an award made in writing and signed by the arbitrator.

(e) The decision shall be final and binding on the Parties in accordance with the *Commercial Arbitration Act* of Canada.

Neither Party may request arbitration in respect of a breach of this Agreement after the fourth anniversary of the day on which the requesting Party first discovered that breach, unless the other Party has agreed in writing to extend the period.

13. GENERAL TERMS AND CONDITIONS

13.1 **Entire Agreement:** This Agreement represents the entire understanding between the Parties as of the effective date hereof, and supersedes all prior communications, negotiations and agreements, written or oral, concerning the NRC Technology.

13.2 **Limits of Agreement:** For greater certainty, the Parties agree that this is not an assignment of ownership of copyright or of patent rights, but merely a licence. This Agreement shall not be construed as creating the relationship of principal and agent, employer and employee, partnership, or joint venture.

13.3 **Amendments:** This Agreement may only be amended by an agreement in writing, signed by the Parties, expressly referring to this Agreement.

13.4 **Severance:** If any provision in this Agreement is found, by a court or arbitration, to be wholly or partly invalid, illegal or unenforceable in any respect, the remainder of this Agreement shall remain enforceable and this Agreement shall be construed as if that provision had never existed. The request to initial each page is not a condition of this Agreement.

13.5 **Waiver:** Failure by a Party to assert rights arising from any default under this Agreement does not constitute a waiver. No waiver shall be effective unless in writing and no written waiver shall operate as a waiver of any subsequent default.

13.6 **Assignment:** This Agreement is personal to the Parties, so that neither its assignment, nor its assumption by a corporation formed by amalgamation of the Licensee with a third party is valid without the NRC's prior written consent, provided that such approval shall not be unreasonably withheld. For the avoidance of doubts, any assignment by the Licensee, change of control, or amalgamation of the Licensee shall require obtaining the prior written consent of the NRC and satisfying all the requirements of the NRC, including but not limited to indemnity, insurance and payment terms stated in Section 3 of this Agreement.

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13.7 **Force Majeure:** Neither Party shall be responsible or liable to the other for failure or delay the performance of this Agreement due to war, fire, accident or other casualty, labour disturbance, act of the public enemy, act of God, or any other contingency beyond that Party's reasonable control. In the event of applicability of this paragraph, the Party affected by such force majeure shall use its best efforts to eliminate, cure or overcome any such causes and resume performance of its obligations as soon as possible.

13.8 **Notices:** Any notice contemplated by this Agreement, unless a different address is subsequently notified by one Party to the other in writing, must be sent to the address stated at the beginning of this Agreement where the Parties are identified, by:

(a) registered mail, and then it is deemed to be an effective notice five (5) days after it is sent;
(b) courier, and then it is an effective notice only when acknowledged by an official receipt; or
(c) by personal delivery to the office of the chief executive officer of the Party, and then it is an effective notice when acknowledged by a signature of either that person or a person with apparent authority to receive messages.

13.9 **Counterpart and Facsimile Execution:** This Agreement may be executed in one or more counterparts and by the different 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 facsimile copy or 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: _____

Michael Sullivan CFO/Principal Executive Officer

SIGNED by the **NRC** at *Montreal, Quebec*, Canada

NATIONAL RESEARCH COUNCIL OF CANADA

Date: _____

Denis Bourbeau - A/Director General
Human Health Therapeutics Research Centre

ANNEX A – Stable Cells

Stable Cells to be provided to the Licensee through the Service Provider

1) CHO $^{2353\ TM}$ stable pool expressing the stabilized trimeric Wuhan spike protein antigen

2) CHO $^{2353\ TM}$ stable pool expressing the stabilized trimeric South African spike protein antigen

For clarity, Additional Stable Cells could be added to the list upon obtaining the NRC's prior written approval, satisfying all the NRC's requirements in this respect and the payment of relevant fees as per stated in section 2.6.2 of this Agreement.

ANNEX B – List of Contractors and Service Providers

List of Contractors

[***]

List of Service Providers

1. Biodextris; 525 Boulevard Cartier O, Laval, QC, Canada H7V 3S8

ANNEX C – List of Affiliates

1. Noachis Terra, Inc.
2. _____

National Research Council Canada | Conseil national de recherches Canada

Technology Licence Agreement
Exclusive/Sole ☐ - Non-Exclusive ☒
Business Confidential – Protected B

ANNEX D – List of technical documentation

To the best of NRC's knowledge, the current list includes available documentation related to the NRC Technology that may be required for Regulatory Approval:

1- Report 00.SR.09: Description of the GMP CHO2353 ™ Cell Line
2- CHO2353 ™ Cell Line Characterization Summary Report (including CoA issued by the external laboratories) (00.SR.10)
3- BSE/TSE Statement
4- Certificate of conformity
5- Product information Sheet
6- Material Safety Data Sheet for the CHO2353 ™ Cell Line
7- Batch records for pDNA manufacture including supporting source documentation
8- Batch Release Check-List

National Research Council Canada | Conseil national de recherches Canada

Amendment one to Technology License Agreement
BUSINESS CONFIDENTIAL – PROTECTED B

THIS IS AN AMENDING AGREEMENT

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 contact: Yves Durocher – Email: yves.durocher@cnrc-nrc.gc.ca
Business contact: Alexandre Serrano – Email: 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 for the NRC Technology described as: ***CHO 2353 ™ Cell Lines.***

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

1. The Agreements shall be read with the amended terms stated below. With respect to all other terms, the Parties confirm the Original Agreement.
2. With reference to Annex A – Stable Cells of the Original Agreement, it is complemented and replaced with the Annex A – Stable Cells enclosed in the present Amendment
3. Expiry date remains the same, *i.e*., July 26, 2041.
4. This Agreement may be executed in one or more counterparts and by the different 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: _____ Per: _____
Michael Sullivan, CFO/Principal Executive Officer

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

NATIONAL RESEARCH COUNCIL OF CANADA

Date: _____ Per: _____
Lakshmi Krishnan, - Director General
Human Health Therapeutics Research Cent

AMENDED ANNEX A – Stable Cells

Stable Cells to be provided to the Licensee through the Service Provider

1) CHO $^{2353\ TM}$ stable pool expressing the stabilized trimeric Wuhan spike protein antigen
2) CHO $^{2353\ TM}$ stable pool expressing the stabilized trimeric South African spike protein antigen
3) CHO $^{2353\ TM}$ stable pool expressing the stabilized trimeric DELTA Variant spike protein antigen

For clarity, Additional Stable Cells could be added to the list upon obtaining the NRC's prior written approval, satisfying all the NRC's requirements in this respect and the payment of relevant fees as per stated in section 2.6.2 of the Original Agreement.

Exhibit 31.1

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 15th day of November, 2021

By: */s/ Michael Sullivan*
Michael Sullivan
Interim 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 15th day of November, 2021

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 September 30, 2021 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Interim Principal Executive Officer

Date: November 15, 2021

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 September 30, 2021 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Michael Sullivan, hereby certify, to the best of my knowledge, that:

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

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

/s/ Michael Sullivan

Name: Michael Sullivan
Principal Financial Officer

Date: November 15, 2021