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

FORM 10-Q

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

For the quarterly period ended June 30, 2023 .
OR

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

For the transition period from _____ to _____

Commission File Number: 001-32188

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

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

4902 Eisenhower Blvd. , Suite 125
Tampa , Florida 33634
(Address of principal executive offices)
813 - 286-7900
(Issuer's telephone number)

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common equity, as of the latest practicable date:

As of August 10, 2023, there were 2,539,385 shares of Common Stock, $0.001 par value, outstanding.

Note Regarding Reverse Stock Splits

We filed an amendment to our Amended and Restated Articles of Incorporation with the Secretary of the State of Florida to effect a reverse split of our authorized and outstanding common stock at a ratio of one for sixty (60) effective January 20, 2023. All historical share and per share amounts reflected in this report have been adjusted to reflect the reverse stock split.

Note Regarding Prior Period Restatements

On April 4, 2023, the Company's management and Audit Committee of the Company's Board of Directors concluded that the unaudited consolidated financial statements for the three and six-month periods ended June 30, 2022 should be restated and should no longer be relied upon. Management reviewed the terms and conditions of the Company's contracts and the payments and concluded that during the three and six-month period ending June 30, 2022 amounts were paid as part of a prepayment arrangement. Management reviewed Accounting Standards Codification Topic 730 Research and Development guidance related to recording initial upfront payments to vendors and determined that the unaudited consolidated financial statements originally reported for the three and six-month periods ended June 30, 2022 classified as research and development expense on the unaudited consolidated statement of operations should have been classified as prepaid expense on the Company's unaudited consolidated balance sheet.

On April 14, 2023 the Company filed an amendment to the Quarterly Report ("Amendment 1") on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on May 13, 2022 (the "Original Form 10-Q"). Amendment 1 was filed for the sole purpose of restating certain financial statements included in the Original Form 10-Q. When referencing prior period comparisons for the three and six-month periods ended June 30, 2022 in this Form 10-Q for the three and six-month periods ended June 30, 2023 the financial information reflects the restated financials as reported in Amendment 1.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.
Consolidated Balance Sheets

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 6,473,822	$ 11,426,785
Other receivables	13,163	-
Prepaid expenses and other current assets	1,611,849	2,844,798
Total current assets	8,098,834	14,271,583
Property and equipment, net	98,456	121,062
Operating lease right-of-use assets	249,256	347,440
Deposits	17,940	17,940
Total assets	$ 8,464,486	$ 14,758,025
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 951,019	$ 1,124,197
Short-term notes payable	-	267,640

Operating lease liabilities - Current	190,242	204,447
Total current liabilities	1,141,261	1,596,284
Long-term liabilities:		
Operating lease liabilities - Long Term	65,752	152,439
Total long-term liabilities	65,752	152,439
Shareholders' equity:		
Preferred stock, no par value; 50,000,000 shares authorized; 5,417,000 and 5,417,000 Series A shares, 4,050,000 and 4,050,000 Series B shares, - 0 - and - 0 - Series C shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	1,592,723	1,592,723
Common stock, $ 0.001 par value; 4,166,666 shares authorized 2,024,657 and 2,024,657 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	2,025	2,025
Additional paid-in capital	197,120,665	196,977,071
Accumulated deficit	(191,457,940)	(185,562,517)
Total shareholders' equity	7,257,473	13,009,302
Total liabilities and shareholders' equity	$ 8,464,486	$ 14,758,025

See accompanying notes.

Oragenics, Inc.
Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
Grant revenue	$ 13,163	$ 30,391	$ 30,187	$ 45,474
Operating expenses:				
Research and development	2,006,696	2,590,032	3,679,272	5,883,693
General and administrative	1,115,785	1,044,334	2,365,048	2,375,883
Local business tax	-	490	-	980
Total operating expenses	3,122,481	3,634,856	6,044,320	8,260,556
Loss from operations	(3,109,318)	(3,604,465)	(6,014,133)	(8,215,082)
Other income (expense):				
Interest income	58,954	15,369	121,155	27,275
Interest expense	(843)	(816)	(4,190)	(4,062)
Miscellaneous income	621	369	1,745	11,333
Total other income, net	58,732	14,922	118,710	34,546
Loss before income taxes	(3,050,586)	(3,589,543)	(5,895,423)	(8,180,536)
Income tax benefit	—	—	—	—
Net loss	$ (3,050,586)	$ (3,589,543)	$ (5,895,423)	$ (8,180,536)
Basic and diluted net loss per share	$ (1.51)	$ (1.85)	$ (2.91)	$ (4.22)
Shares used to compute basic and diluted net loss per share	2,024,766	1,939,913	2,024,766	1,939,913

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, 2022	2,024,657	$ 2,025	9,467,000	$1,592,723	$196,977,071	($ 185,562,517)	$ 13,009,302
Compensation expense relating to option issuances	—	—	—	—	79,966	—	79,966
Net loss	—	—	—	—	—	(2,844,837)	(2,844,837)
Balances at March 31, 2023	2,024,657	2,025	9,467,000	1,592,723	197,057,037	(188,407,354)	10,244,431
Compensation expense relating to option issuances	—	—	—	—	63,628	—	63,628
Net loss	—	—	—	—	—	(3,050,586)	(3,050,586)
Balances at June 30, 2023	2,024,657	$ 2,025	9,467,000	$1,592,723	$197,120,665	($ 191,457,940)	$ 7,257,473

	Common Stock		Preferred Stock		Additional Paid In	Accumulated	Total Shareholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balances at December 31, 2021	2,002,946	$ 2,003	16,017,000	$2,656,713	$195,101,611	($ 171,274,128)	$ 26,486,199

Compensation expense relating to option issuances	—	—	—	—	90,247	—	90,247
Net loss	—	—	—	—	—	(4,590,993)	(4,590,993)
Balances at March 31, 2022	2,002,946	$ 2,003	16,017,000	$2,656,713	$195,191,858	$ 175,865,121)	($ 21,985,453
Compensation expense relating to option issuances	—	—	—	—	278,988	—	278,988
Net loss	—	—	—	—	—	(3,589,543)	(3,589,543)
Balances at June 30, 2022	2,002,946	$ 2,003	16,017,000	$2,656,713	$195,470,846	$ 179,454,664)	($ 18,674,898

See accompanying notes.

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

	For the Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (5,895,423)	$ (8,180,536)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	22,606	18,847
Gain on sale of property and equipment	-	(10,964)
Stock-based compensation expense	143,594	369,235
Changes in operating assets and liabilities:		
Other receivables	(13,163)	6,987
Operating Lease Right of Use Assets	98,184	-
Prepaid expenses and other current assets	1,232,949	(1,555,350)
Deposits	-	-
Accounts payable and accrued expenses	(274,070)	332,024
Net cash used in operating activities	(4,685,323)	(9,019,757)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	-	12,000
Purchase of property and equipment	-	(87,047)
Net cash used in investing activities	-	(75,047)
Cash flows from financing activities:		
Payments on short-term notes payable	(267,640)	(303,416)
Net cash used in financing activities	(267,640)	(303,416)
Net decrease in cash and cash equivalents	(4,952,963)	(9,398,220)
Cash and cash equivalents at beginning of period	11,426,785	27,265,703
Cash and cash equivalents at end of period	$ 6,473,822	$ 17,867,483
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,347	$ 4,062

See accompanying notes.

Oragenics, Inc.
Notes to Consolidated Financial Statements
(Unaudited)

1. Organization

Oragenics, Inc. (the “Company” or “we”, or “our”) is focused on the development of the NT-CoV2-1 intranasal vaccine candidate to combat the novel Severe Acute Respiratory Syndrome coronavirus (“SARS-CoV-2”) and further development of effective treatments for novel antibiotics against infectious disease.

2. Basis of Presentation

The accompanying unaudited interim consolidated financial statements as of June 30, 2023, the December 31, 2022, and the three and six-months ended June 30, 2023 and 2022, have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim consolidated financial information and with the instructions to Form 10-Q and Article 8 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by US GAAP for complete consolidated financial statements. In the opinion of management, the accompanying consolidated financial statements include all adjustments, consisting of normal recurring accruals, necessary for a fair presentation of the financial condition, results of operations and cash flows for the periods presented. The results of operations for the interim period ended June 30, 2023, are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2023, or any future period.

Prior Period Restatements

On April 4, 2023 the Company’s management and Audit Committee of the Company’s Board of Directors concluded that the unaudited consolidated financial statements for the three and six-month periods ended June 30, 2022 should be restated and should no longer be relied upon. Management reviewed the terms and conditions of the Company’s contracts and the payments and concluded that during the three and six-month periods ending June

30, 2022 amounts were paid as part of a prepayment arrangement. Management reviewed Accounting Standards Codification Topic 730 Research and Development guidance related to recording initial upfront payments to vendors; and determined that the unaudited consolidated financial statements originally reported for the three and six-month periods ended June 30, 2022 classified as research and development expense on the unaudited consolidated statement of operations that should be classified as prepaid expense on the Company's unaudited consolidated balance sheet.

On April 14, 2023 the Company filed Amendment 1 on Form 10-Q/A with the SEC. Amendment 1 was filed for the sole purpose of restating certain financial statements included in the Original Form 10-Q. When referencing prior period comparisons for the three and six-month periods ended June 30, 2022 in this Form 10-Q the financial information reflects the restated financials as reported in Amendment 1.

Going Concern Consideration

These consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2022, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 17, 2023. The Company has incurred recurring losses and negative cash flows from operations since inception. To date, the Company has not generated significant revenues from operations. The Company incurred a net loss of $ 5,895,423 and used cash of $ 4,685,323 in its operating activities during the six months ended June 30, 2023. As of June 30, 2023, the Company had an accumulated deficit of $ 191,457,940 .

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at June 30, 2023 will be sufficient to meet the business objectives as presently structured only through the fourth quarter of 2023. As such, there is substantial doubt that we can continue as a going concern beyond that date. As a result, the Company has implemented certain cost-saving initiatives, including reducing our efforts and staff focused on our lantibiotics program, which are expected to negatively impact the development of our lantibiotics program. See, "Risk Factors."

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

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

3. Significant Accounting Policies

Basis of Consolidation

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

New Accounting Standards

There are no additional accounting pronouncements issued or effective during the three months ended June 30, 2023, that have had, or are expected to have, a material impact on our consolidated financial statements.

Use of Estimates

The preparation of consolidated financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. The principal area of estimation reflected in the consolidated financial statements are estimates for research and development expenses and related prepaid and accrued expenses, which are based on the percentage of completion of the Company's contracts with Contract Research Organizations.

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations. Adjustments to the Consolidated Balance Sheet and Consolidated Statement of Cash Flows for the six-month period ended June 30, 2022 were as follows:

- Deposits of $ 17,940 were reclassified from Prepaid Expenses and other current assets to Other Assets.
- Changes in Operating Lease Right of Use Assets of $ 45,921 was reclassified from Accounts Payable and Accrued Expenses into its own account.
- Changes in Operating Lease Liabilities of ($ 47,327) was reclassified from Accounts Payable and Accrued Expenses into its own account.

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

Stock-Based Compensation

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

Warrants

The Company used the Black-Scholes Option Pricing Model in calculating the 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. All references to common stock for the comparative three and six-month periods ended June 30, 2022, have been adjusted to reflect the effect of the reverse split. 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 there is a minimal credit risk on cash and cash equivalents. Cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which the Company holds its cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets.

Grant Revenue

Grant revenues are derived from a small business innovation research grant in the amount of $ 250,000 (“Computer-aided Design for Improved Lantibiotics” R41GM136034. The Company recognizes grant revenue as reimbursable grant costs are incurred up to the pre-approved award limits within the budget period. The costs associated with these reimbursements are reflected as a component of research and development expenses in the accompanying consolidated statement of operations. The remainder of the grant will be recognized in July of 2023.

4. Property and Equipment, net

Property and equipment, net consists of the following as of June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Furniture and fixtures	$ 20,742	$ 20,742
Laboratory equipment	676,744	676,744
Leasehold improvements	487,871	487,871
Office and computer equipment	298,944	298,944
	1,484,301	1,484,301
Accumulated depreciation and amortization	(1,385,845)	(1,363,239)
Property and equipment, net	$ 98,456	$ 121,062

Depreciation and amortization expense for the three months ended June 30, 2023 and 2022 was $ 11,303 and $ 10,379 respectively. Depreciation and amortization expense for the six months ended June 30, 2023 and 2022 was $ 22,606 and $ 18,847 respectively.

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of June 30, 2023, and December 31, 2022:

	June 30, 2023	December 31, 2022
Accounts payable trade	$ 590,576	$ 246,690
Accrued Expense	334,441	812,861
Professional fees	-	31,101
Vacation	26,002	33,545
Total accounts payable and accrued expenses	$ 951,019	$ 1,124,197

6. Short-Term Notes Payable

The Company had the following short-term notes payable as of June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Directors’ and officers’ liability insurance financing of $ 528,429 and $ 600,169 due in monthly installments of $ 54,366 and $ 61,496 including principal and interest at 6.24 % and 5.34 % through May 24, 2024 and May 24, 2023 , respectively	$ -	$ 267,640

The Company’s policy renewals will be completed in subsequent periods and the Company will evaluate if premium financing is necessary at that time. The Company also maintains a product liability insurance policy which has been renewed in subsequent periods without premium financing.

7. Prepaid Expense and Other Current Assets

Schedule of Prepaid Expense and Other Current Assets at June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Prepaid research and expense	$ 1,455,456	$ 2,471,809
Prepaid insurance	56,393	372,989
Prepaid financing costs	75,000	-
Other prepaid costs	25,000	-
Total accounts payable and accrued expenses	$ 1,611,849	$ 2,844,798

As of June 30, 2023 and December 31, 2022, the Company had approximately $ 1.6 million and $ 2.8 million in prepaid expenses, respectively. The balance at June 30, 2023 reflects approximately $ 1.5 million of prepaid expense to third-party vendors for research and development to be completed.

8. Shareholders' Equity

Common Stock

Reverse Stock Split

On December 22, 2022, the Board of Directors approved an amendment to our Amended and Restated Articles of Incorporation to effect a reverse stock split of our common stock by a ratio of one for sixty . The Company's common stock began trading on a split-adjusted basis on January 23, 2023. All references to common stock for the comparative three and six-month periods ended June 30, 2022, have been adjusted to reflect the effect of the reverse split. The stock split was also reflected in the December 31, 2022 stock amounts. As a result of the reverse stock split, the Company's common stock began trading on a split-adjusted basis on January 23, 2023.

Shares issued under At-The-Market ("ATM") program

For the three and six-month periods ended June 30, 2022 and 2023 the Company did not issue any shares of common stock under its ATM program.

During the three-month period ended December 31, 2022, the Company issued 6,544 shares of common stock under its ATM Program which generated gross proceeds of approximately $ 72,000 , The net proceeds of the offering were for use in connection with the Company's pre-clinical development of its SARS-CoV-2 vaccine candidates, Terra CoV-2 and NT-CoV2-1, and its lantibiotics program and for general corporate purposes, including research and development activities, capital expenditures and working capital.

On December 19, 2022, the Company sent written notice of termination to A.G.P./Alliance Global Partners ("AGP"), pursuant to the terms of the Company's Sales Agreement with AGP in connection with the Company's ATM Program. The termination took effect on December 29, 2022. As a result of the termination, the Company will not, and during the six months ended June 30, 2023 did not, consummate any further sale of its common stock through the AGP Sales Agreement.

On February 24, 2023 the Company entered into an ATM with Ladenburg Thalmann & Co. Inc ("Ladenburg") to sell shares of its common stock. The Company intends to use the proceeds from the ATM to continue funding its pre-clinical development of its SARS-CoV-2 vaccine candidates, Terra CoV-2 and NT-CoV2-1 and its lantibiotics program and for the general corporate purposes, including capital expenditures, working capital, and research and development activities.

Other Share Issuances

During the three and six-month periods ended June 30, 2022 and 2023 the Company issued no additional shares of common stock.

During the three-month period ended September 30, 2022 and prior to the reverse stock split, the holders of 4,000,000 shares of the Company's Series A Convertible Preferred Stock, and 2,550,000 shares of the Company's Series B Convertible Preferred Stock converted the Series A Convertible Preferred Stock into an aggregate of approximately 15,000 shares of common stock.

During the twelve-months ended December 31, 2022, the Company issued 13,019 shares of common stock in connection with the exercise of stock options which generated gross proceeds of $ 363,139 .

Preferred Stock

Issuance of Series A Convertible Preferred Stock Financing

In May of 2017 we entered into a securities purchase agreement to sell up to $ 3 million of Series A Convertible Preferred Stock. The full $ 3 million of Preferred Stock, after giving effect to the reverse stock splits and previous conversions, is convertible into 9,029 shares of our common stock based on a fixed conversion price of $ 150.00 per share on an as-converted basis. In addition, and after giving effect to the reverse stock split, we issued warrants to purchase an aggregate of approximately 17,742 shares of common stock. The warrants have a term of seven years from the date of issuance and have an exercise price of $ 186.00 per share. Proceeds from the Series A Preferred Stock and any cash proceeds from the exercise of any warrants will be used for general corporate purposes, including working capital.

The Series A Preferred Stock also includes certain demand registration rights, piggyback registration rights and liquidation preference rights. On May 10, 2017, we filed a Certificate of Designations of Preferences, Rights and Limitations of Series A Preferred Stock (the "Certificate of Designation") with the Secretary of State of the State of Florida. Except as otherwise required by law, as long as any shares of Series A Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A Preferred Stock, (c) increase the number of authorized shares of Series A Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designation), the holders of Series A Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series A Preferred Stock if all outstanding shares of Series A Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A Preferred Stock is classified as permanent equity.

The Series B Non-Voting, Convertible Preferred Stock Financing

On November 8, 2017, we completed a private placement of $ 3.3 million of Series B Non-Voting, Convertible Preferred Stock (the “Series B Convertible Preferred Stock”).

The full $ 3.3 million of Series B Convertible Preferred Stock, and after giving effect to the reverse stock splits and the previous conversions, is convertible into 13,500 shares of our common stock, based on a conversion of one share of Series B Preferred Stock into two shares of Common Stock. The purchase price per share of the Series B Preferred Stock is represented by $ 150.00 per share of the Common Stock on an as converted basis. In addition, and after giving effect to the reverse stock split, we issued to the investors in the private placement accompanying common stock purchase warrants to purchase an aggregate of approximately 17,742 shares of Common Stock. The warrants have a term of seven years from the date of issuance, and after giving effect to the reverse stock split, have an exercise price of $ 186.00 per share.

In connection with the Series B Preferred Financing, we filed a Certificate of Designation and Rights of Series B Convertible Preferred Stock with the Secretary of State of the State of Florida, to be effective November 8, 2017.

Except as otherwise required by law, the Series B Preferred Stock shall have no voting rights. However, as long as any shares of Series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series B Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series B Preferred Stock, (c) increase the number of authorized shares of Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing.

The Series B Preferred Stock ranks (i) on par with the Common Stock and Series A Preferred Stock as to dividend rights and (ii) on par with Series A Preferred Stock and senior to the Common Stock as to distribution of assets upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary, the holders of Series B Preferred Stock shall be entitled to receive out of the assets, on par with the holders of Series A Preferred Stock and in preference to the holders of the Common Stock, an amount of cash equal to the greater of (i) the product of the number of shares of Series B Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation in respect of Common Stock issuable upon conversion of such shares of Series B Preferred Stock if all outstanding shares of Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series B Preferred Stock is classified as permanent equity.

9. Warrants

The Company’s outstanding and exercisable warrants as of June 30, 2023 are presented below:

Exercise Price	Total Warrants Outstanding	Exercisable Warrants Outstanding	Expiration Date
$ 54.00	32,033	32,033	3/25/2024
$ 186.00	5,135	5,135	5/10/2024
$ 186.00	6,694	6,694	7/25/2024
$ 186.00	10,888	10,888	11/8/2024
$ 75.00	153,334	153,334	5/1/2025
$ 60.00	52,911	52,911	7/17/2025
$	260,995	260,995	

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

10. Stock Compensation Plan

On February 25, 2022, the Company held its 2020 Annual Meeting. At the 2020 Annual Meeting, the shareholders of the Company approved and ratified the Company’s 2021 Equity Incentive Plan (the “2021 Incentive Plan”), which is a successor to the 2012 Incentive Plan. The 2021 Incentive Plan provides the aggregate number of shares of Common Stock that may be issued under the 2021 Plan will not exceed the sum of (i) 166,667 new shares, (ii) the number of shares remaining available for the grant of new awards under the 2012 Incentive Plan as of immediately prior to the effective date of the 2021 Incentive Plan, and (iii) certain shares subject to outstanding awards granted under the 2012 Incentive Plan that may become available for issuance under the 2021 Incentive Plan, as such shares become available from time to time. As of December 31, 2022, an aggregate of 139,091 shares of common stock are covered by outstanding option awards and 148,455 shares of common stock are available for future awards under the 2021 Incentive Plan.

Options are granted at the fair market value of the Company’s stock on the date of grant which determines the exercise price after the completion of the vesting period. Options can vest either immediately or over a period of up to three years from their respective grant dates and expire 10 years from the date of grant. As of June 30, 2023 and December 31, 2022, the Company did not award any stock appreciation rights under the 2021 Incentive Plan.

Total compensation cost related to stock options was approximately $ 63,628 and $ 278,988 for the three months ended June 30, 2023 and 2022, respectively. Total compensation cost related to stock options was approximately $ 143,594 and $ 369,235 for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, there was approximately $ 118,874 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of less than one year.

During the six-months ended June 30, 2023, the Company granted 7,000 stock options to the Chief Financial Officer as an onboarding award. The exercise price, determined by the stock price close on March 7, 2023, was $ 4.00 per share. The fair value of this award was $ 3.92 per share of common stock which is used to expense the option over the vesting period. This fair value was determined using the Black Scholes Option Pricing model, which values options based on the stock price at the grant date, the expected life of the option, the estimated volatility of the stock, the expected dividend payments, and the risk-free interest rate over the life of the option. The assumptions used in the Black-Scholes Option Pricing model were as follows for stock options granted in the six-month period ended June 30, 2023:

	Six-months ended June 30, 2023
Risk free interest rate	4.0%

Expected volatility of common stock	143.0%
Dividend yield	0.0%
Expected life of options	10 years

11. License Agreements

Inspirevax License

On February 23, 2023, the Company entered into a Commercial License Agreement (the "License Agreement") with Inspirevax Inc. ("Inspirevax") pursuant to which Inspirevax granted the Company an exclusive worldwide license to use Inspirevax's inventions, patents, trade secrets, know-how, copyright, biological material, designs, and/or technical information created by or on behalf of Inspirevax (the "Inspirevax Technologies") relating to its novel lipid-protein based intranasal adjuvants, to make, research, and develop an intra-nasal vaccine in combination with an antigen ("Combination Product") to be used in an intranasal vaccine for use against diseases caused by coronaviruses and any genetic variants thereof to be sold by us. The Company agreed to pay in consideration for the License Agreement an upfront signing fee and to certain milestone payment obligations.

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, the Company holds 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.

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. The License Agreement was subsequently amended in September and December of 2021, again in February and July of 2022, and most recently in April of 2023. Consolidated the amendments included the following changes to the License Agreement i) to include the Delta and Omicron variants, ii) provided terms to broaden the non-exclusive field of use to include all diseases caused by coronaviruses and any genetic variants thereof, additionally iii) removed certain protocols and reagents from the License Agreement, and iv) included amendments to remove any license fees owed by the Company to the NRC related to the returned protocols and reagents.

12. Commitments and Contingencies

Additional Consideration−Noachis Terra Inc.("NTI") Acquisition.

In connection with the Company's acquisition of NTI, the Company is obligated to pay the former sole shareholder of NTI contingent consideration based upon the exercise of certain of the Company's outstanding warrants as follows: (i) twenty percent (20 %) of the cash proceeds received by the Company upon exercise of the Company's warrants carrying an exercise price of $ 45.00 and $ 54.00 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 $ 60.00 , in each case, for so long as the warrants remain outstanding.

The Company's previously issued warrants carrying an exercise price of $45.00 have expired by their terms. As a result, no additional consideration will be due to the former sole shareholder of NTI relating to these warrants .

At December 31, 2021, 41,210 warrants had been exercised as follows: (i) 6,000 shares at an exercise price of $ 60.00 per share and (ii) 35,210 at an exercise price of $ 54.00 per share.

As of the six-month period ended June 30, 2023, there are 32,033 warrants outstanding carrying an exercise price of $ 54.00 that expire on March 25, 2024 and 52,911 warrants outstanding carrying an exercise price of $ 60.00 that expire on July 17, 2025 .

Inspirevax

As consideration for the License Agreement with Inspirevax the Company will be subject to certain milestone payments related to various events including but not limited to: (a) the Company's decision for an appropriate nasal spray device, (b) phase 2a and 2b/3 clinical trials and patient participation, (c) certain license applications submitted to the FDA; (d) certain filing events for marketing authorizations out of the United States; and (e) certain metrics for sales within the United States, Europe and other countries or regions. Additionally, the Company is required to pay to Inspirevax certain royalties based upon net sales and subject to revenue limitations at which time the royalty amount will decrease. The amount of the milestone obligations could range from $ 0.1 million to $ 7.25 million; the Company evaluates the likelihood of triggering any milestone obligations and records the liabilities on the consolidated financial statements as they are incurred.

On May 25, 2023 the Company and Inspirevax agreed to amend certain payment terms of the License Agreement related to the purchase of biological materials. The amended payment terms provide the Company with longer periods to make payment and are based on the earlier of certain vaccine development milestones or June 30, 2024.

Unless terminated earlier, the License Agreement will terminate the later of (i) twenty (20) years from the first commercial sale of a product, (ii) the last date a product is covered by a valid patent claim, or (iii) the expiration of regulatory exclusivity. The Company may terminate the License Agreement by giving thirty (30) days written notice to Inspirevax. Either party may terminate, if the other party defaults or is in breach of the License Agreement, provided that if the defaulting party cures the breach within sixty (60) days after the notice is given, the License Agreement shall continue in full force and effect. The License Agreement contains customary confidentiality obligations.

NIH License

Under the terms of the NIH License Agreement, 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

As consideration for the grant of the NRC 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 (already paid). 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 certain countries, additional countries may be requested by us at our expense. In addition, the Company is required to provide certain indemnifications to the NRC and its employees.

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.

Three-Way Collaborative Agreement

In May of 2023 the Company entered into a Collaborative Research Agreement (the “Collaboration”) with Inspirevax, and the NRC (the “Collaborators”). The Collaboration received non-dilutive funding from Consortium Québécois Sur La Découverte Du Médicament (the “CQDM”) a not-for-profit corporation governed by Canada created to promote, stimulate, and support drug research, development and discovery. The CQDM also provides funding for drug research and discovery projects. The project is budgeted to cost approximately $ 1.7 million Canadian dollars over 27 months. Each collaborator is responsible for funding a portion of the project with payments made upon certain milestones, the CQDM grant award will fund approximately 40% of the budgeted project costs with the Collaborators.

13. Leases

Lab Facility-Alachua. The Company began leasing this office location from a real estate developer for a term of five years beginning in December 2014. In June of 2019, the Company entered into an amendment for the Alachua facility for a term of five years beginning in December of 2019. Under the amended lease agreement, the rental payments range from $ 12,870 per month to $ 13,338 per month. Total rental expense for the Alachua facility during the six-months ended June 30, 2023 was approximately $ 85,230 . The lease may be terminated prior to its stated expiration date upon the payment of nine-months rent.

Corporate Office-Tampa. In November of 2016, the Company entered into an amendment for the leased office space for corporate personnel located in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space was thirty-six months commencing on March 1, 2017. The Company entered into amendments extending the term of the lease in November 2019 and August 2022. The lease expires on February 29, 2024 . Lease payments are $ 4,944 per month inclusive of insurance, taxes, and utilities. Total rent expense for the three and six-months ended June 30, 2023 was $ 16,878 and $ 33,578 , respectively.

	For the Six Months Ended June 30, 2023	For the Twelve Months Ended December 31, 2022
Weighted Average Remaining Lease Term In Years		
Operating leases	1.21	1.72
Weighted Average Discount Rate		
Operating leases	5.77%	5.78%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2023	109,690
2024	156,605
2025	-
Total	$ 266,295
Less: effect of discounting	(10,301)
Present value of lease liabilities	$ 255,994

The cost component of operating leases is as follows:

	For the Six Months Ended June 30, 2023	For the Six Months Ended June 30, 2022
Operating lease cost	$ 116,098	$ 114,259
Short-term lease cost	-	1,965
Total lease cost	$ 116,098	$ 116,224

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

	For the Six Months Ended June 30, 2023	For the Six Months Ended June 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 118,807	$ 117,350

14. Subsequent Events

Securities Purchase Agreement

On August 4, 2023 the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with two healthcare-focused investors, pursuant to which the Company agreed to issue in a private placement (the "Offering"), an aggregate of (i) 404,728 shares of the Company's common stock, $ 0.001 par value (the "Common Stock"), and (ii) 404,728 shares of Series E Mirroring Preferred Stock (the "Series E Preferred Stock"). For each share of Common Stock purchased by an investor, the investor will receive one share of Series E Preferred Stock.

The gross proceeds from the offering are approximately $ 850,000 . The Company intends to use the net proceeds from the offering for general corporate purposes.

The Common Stock and Series E Preferred Stock sold in the Offering were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Common Stock and Series E Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

The Purchase Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, other obligations of the parties and termination provisions.

Series E Preferred Stock

In connection with the Securities Purchase Agreement referenced above, the Company filed a Certificate of Designation with the Secretary of State for the State of Florida (the "Series E Certificate of Designation") designating 404,728 shares out of the authorized but unissued shares of its preferred stock as Series E Preferred Stock.

The descriptions of the Certificate of Designation and Purchase Agreement are qualified by reference to the full text of such documents, which were attached to the Form 8-K as Exhibits 3.1 and 10.1 respectively, filed with the Securities and Exchange Commission on August 7, 2023.

Restricted Stock Award

On August 8 2023, the Compensation Committee and Board of Directors approved restricted stock awards to certain of our executive officers under the Company's 2021 Equity Incentive Plan, consisting of 25,000 shares to our Chief Executive Officer, Ms. Kimberly Murphy, with 20,000 shares to vest immediately and 5,000 shares to vest within six (6) months from date of the award and 15,000 shares to our Chief Financial Officer, Ms. Janet Huffman, with 10,000 shares to vest immediately and 5,000 shares to vest within six (6) months from date of the award. The restricted stock awards are subject to the terms and conditions of the Company's form of restricted stock award agreement which includes, earlier vesting upon a change in control of the Company. An additional 100,000 shares of common stock were awarded to directors of the Company with 80,000 shares to vest immediately and 20,000 shares to vest within six (6) months from date of the award.

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, 2022 filed on April 17, 2023.

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

Forward-Looking Statements

This Quarterly Report on Form 10-Q includes "forward-looking" statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements are not historical facts, but are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. These forward-looking statements include statements about our strategies, objectives and our future achievement. To the extent statements in this Quarterly Report involve, without limitation, our expectations for growth, estimates of future revenue, our sources and uses of cash, our liquidity needs, our current or planned clinical trials or research and development activities, product development timelines, our future products, regulatory matters, expense, profits, cash flow balance sheet items or any other guidance on future periods, these statements are forward-looking statements. These statements are often, but not always, made through the use of word or phrases such as "believe," "will," "expect," "anticipate," "estimate," "intend," "plan," and "would. "These forward-looking statements are not guarantees of future performance and concern matters that could subsequently differ materially from those described in the forward-looking statements. Actual events or results may differ materially from those discussed in this Quarterly Report on Form 10-Q. Except as may be required by applicable law, we undertake no obligation to update any forward-looking statements or to reflect events or circumstances arising after the date of this Report. Important factors that could cause actual results to differ materially from those in these forward-looking statements are in the section entitled "Risk Factors" in the most recent Annual Report on Form 10- K filed with the Securities and Exchange Commission, and the other risks and uncertainties described elsewhere

in this report as well as other risks identified from time to time in our filings with the Securities and Exchange Commission, press releases and other communications. In addition, the statements contained throughout this Quarterly Report concerning future events or developments or our future activities, including concerning, among other matters, current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain sufficient funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring.

Overview

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

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

Following our May 2020 acquisition of one hundred percent (100%) of the total issued and outstanding common stock of NTI we are focused on the development and commercialization of a vaccine product candidate to provide long-lasting immunity from SARS-CoV-2, which causes COVID-19. NTI is a party to a worldwide, nonexclusive intellectual property and biological materials license agreement with the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute within the National Institutes of Health ("NIH"), relating to certain research, patent applications and biological materials involving pre-fusion stabilized coronavirus spike proteins and their use in the development and commercialization of a vaccine to provide specific, long lasting immunity from SARS-CoV-2. Since the acquisition we have conducted testing in animal models, including SARS-CoV-2 challenge studies in hamsters, using specific formulations for intramuscular administration (our Terra CoV-2 vaccine candidate) and intranasal administration (our NT-CoV2-1 vaccine candidate), both based on the NIAID pre-fusion stabilized spike protein antigens. Following consideration of a number of factors, including but not limited to the competitive landscape, we determined to bring the intranasal vaccine candidate NT-CoV2-1, into further development due to the greater differentiation versus current COVID-19 vaccines and the potential benefits of intranasal over intramuscular administration. We believe these benefits could include a higher reduction of transmission of SARS-CoV-2 and would offer a needle-free delivery option. We therefore are currently focusing our development efforts on our more highly differentiated NT-CoV2-1 vaccine candidate.

On July 26, 2021, we entered into a licensing agreement with the National Research Council ("NRC") that enables us to pursue the development of next-generation vaccines against the SARS-CoV-2 virus and its variants. The license was subsequently amended to: include the Omicron variant, broaden the non-exclusive field of use to include all diseases caused by coronaviruses, and any genetic variants thereof, to add a research protocol developed by the NRC, and to add reagents as part of the NRC Technology licensed by us. The NRC technologies, in combination with the licensed technologies from the U.S. NIH used in our NT-CoV2-1 vaccine candidate, provide us with a platform that can generate cell lines for high-yield production of spike protein antigens for existing and emerging variants of concern. This platform should allow production of cell lines within six to eight weeks of spike gene sequence availability, compared with six to nine months for traditional production of such cell lines. The NRC technologies, developed with support from the NRC's Pandemic Response Challenge Program, are expected to enable expedited evaluation of SARS-CoV-2 antigen candidates in pre-clinical and clinical studies.

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other body-systems, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2, which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). As of August 8, 2023, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 769 million and the number of deaths directly attributed to COVID-19 have exceeded 6.9 million. Pfizer/BioNTech received FDA approval for their COVID-19 vaccines in August of 2021 and the Moderna vaccine in January 2022. In July of 2022, the FDA granted EUA for the Novavax COVID-19 vaccine. FDA granted EUA for Janssen's COVID-19 vaccine in February of 2021 and revoked the EUA on June 1, 2023. On April 18, 2023, FDA amended the EUA of both Moderna and Pfizer/BioNTech Bivalent (Original and Omicron BA.4/BA.5 strains) to be used for all doses administered to individuals six months of age and older. Available vaccines have reduced the rates of hospitalization and death due to COVID-19 in vaccinated individuals, but the transmission levels even in vaccinated individuals has allowed SARS-CoV-2 variants to continue to circulate. We believe given the size of the worldwide spread of COVID-19 that even with additional vaccines available, there will be demand for the highly differentiated NT-CoV2-1 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license and with our NRC license and our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health issue. We believe our NT-CoV2-1 vaccine holds the possibility of playing an important role in addressing this issue.

Coronaviruses, such as SARS-CoV-2, possess signature protein spikes on their outer capsule. Our NIAID license covers patents and data on a vaccine candidate that were created based on a stabilized pre-fusion spike trimeric protein. By stabilizing the spike protein in the pre-fusion state, the number of immunogenic centers is increased thereby allowing for a greater likelihood of successful antibody binding, resulting in an improved immunogenic response. Spike protein antigens stabilized in the pre-fusion state have been used successfully in the leading COVID-19 vaccines from Pfizer/BioNTech and Moderna, which we believe reduces the risk of using the same approach in our NT-CoV2-1 vaccine candidate. The 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 pre-clinical biologics product development, has extensive experience building CHO cell lines for recombinant proteins, such as monoclonal antibodies. Aragen successfully inserted the NIH pre-fusion spike protein gene sequence into a CHO cell line and Oragenics is currently producing Phase 1 clinical material based upon this cell line.

We entered into both a material transfer agreement and a non-exclusive research license agreement with Inspirevax for the use of intranasal mucosal adjuvants in our NT-CoV2-1 vaccine candidates. Regarding the intranasal mucosal adjuvants of interest, BDX300 and BDX301 are proteosome-based adjuvants comprised of proteins and lipopolysaccharides with improved attributes including enhanced immune response, manufacturing efficiency and the benefits of intranasal vaccine administration. The non-exclusive license agreement allows for the collaboration and research regarding the intranasal delivery of vaccine during clinical development with the opportunity to enter into a commercial agreement upon regulatory approval of the intranasal vaccine. The NT-CoV2-1 vaccine containing Inspirevax's intranasal mucosal adjuvant BDX301 has been studied in pre-clinical animal studies, including hamster viral challenge studies and mouse immunogenicity studies. A rabbit toxicology study has been initiated and is required for regulatory approval prior to the Phase 1 clinical study.

A Non-Exclusive Research License Agreement with Inspirevax was executed in February 2022. This agreement granted the Company non-exclusive rights to conduct non-clinical and clinical research and trials in relation to vaccines comprising the BDX300 or BDX301 adjuvants to prevent or treat diseases caused by coronaviruses and genetic variants thereof.

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

In March of 2022, following a positive assessment of a rabbit-based pilot study, we initiated a Good Laboratory Practice toxicology study to evaluate the safety profile and immunogenicity of NT-CoV2-1 in rabbits. This important preclinical study is designed to provide data required to advance our intranasal vaccine candidate into human clinical studies. Based on the findings of the final toxicology report, including a full histopathology evaluation, we were able to confirm a safety and immunogenicity profile that further support our plan to submit regulatory filings required to progress to a Phase 1 clinical study.

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

On February 23, 2023, we entered into a Commercial License Agreement with Inspirevax, Inc. for its novel intranasal mucosal adjuvant, BDX301, for the development of NT-CoV2-1, our lead intranasal COVID-19 vaccine candidate. Under the exclusive licensing agreement, we are required to use our best efforts to develop NT-CoV2-1 with Inspirevax's novel BDX301 intranasal mucosal adjuvant. We have also formed a Joint Development Committee (JDC) with Inspirevax comprising representatives of both companies to oversee the development efforts. We will be subject to clinical, regulatory and commercial milestone payments, as well as tiered royalty payments. Additionally, the agreement provides a certain period of time for the companies to expand their focus to pursue the development of additional intranasal vaccine candidates using Inspirevax's adjuvants.

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

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

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

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

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

Through assessment of a variety of factors including our pre-clinical testing to date, the expected benefits noted above, evolving variants and available vaccines in use, we determined to focus our development efforts on the intranasal delivery of our vaccine product candidate, NT-CoV2-1, which we believe is more highly differentiated than the currently available and late-stage COVID-19 vaccines. We are currently evaluating formulation options and considering regulatory pathways to advance the program. In connection therewith, we are strategically assessing multiple opportunities inclusive of further regulatory guidance and requirements, and the potential implications thereof. As a result, we now anticipate being in a position to file an IND application in the United States and/or a Clinical Trial Application in Canada and to thereafter commence a Phase 1 clinical study with NT-CoV2-1 in the back half of 2023.

We expect to use our currently available cash resources to continue to advance the development of NT-CoV2-1 through IND-enabling studies and commencement of a Phase 1 clinical trial with further clinical development being contingent upon the receipt of additional funding, including non-dilutive government grant funding which we continue to pursue, or partnering or out-licensing opportunities.

On June 5, 2023, we announced the award of a grant from CQDM, a Canadian bioresearch consortium, for the collaborative development of a variant-agnostic COVID-19 protein subunit vaccine candidate. The project, which aims to build upon Oragenics' current lead intranasal vaccine candidate NT-CoV2-1, is a collaboration with the National Research Council of Canada (NRC) and Inspirevax. The new source of non-dilutive funding is expected to help address the evolving SARS-CoV-2 virus by working to develop broadly protective antigens designed to protect against current and future variants. We believe our pan-coronavirus vaccine candidate presents a potential universal solution to the evolving nature of SARS-CoV-2 and potentially future coronaviruses.

The grant awarded by CQDM is expected to help Oragenics fund the development of two to four well-characterized stable CHO pools expressing new, cross-protective vaccine antigens with well-established preclinical efficacy using intranasal immunization. These antigens are expected to be rapidly deployable in next-generation vaccine formulations by leveraging the NRC's advanced manufacturing platform currently utilized by Oragenics and previously developed for the reference strain SARS-CoV-2 spike antigen.

Our Antibiotic Product Candidate - Oragenics Derived Compound (ODC-x)

Members of our scientific team discovered that a certain bacterial strain of *Streptococcus mutans,* produces Mutacin 1140 (MU1140), a molecule belonging to the novel class of antibiotics known as lantibiotics. Lantibiotics, such as MU1140, are highly modified peptide antibiotics made by a small group of Gram-positive bacterial species. Over 60 lantibiotics have been discovered, to date. We believe lantibiotics are generally recognized by the scientific community to be potent antibiotic agents.

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

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

The timing of the filing of an IND regarding any future lantibiotic candidate is subject to our having sufficient available human, material and financing capital, which includes research subjects, both animal and human, given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. Based upon the current funding we expect to reduce our 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 until such time as we raise additional capital.

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

On March 14, 2023, we announced favorable findings from third party laboratory testing of several compounds in our lantibiotics platform to combat multiple pathogens despite the resistance of those pathogens to standard-of-care antibiotics. Lantibiotics are a novel class of antibiotics with the potential to treat serious, life-threatening infections. Through its platform, Oragenics has created more than 700 potential lantibiotic structures. Our lantibiotics platform is focused on the development of new antibiotics effective against certain pathogens including Enterococcus faecium (VRE) and Staphylococcus aureus (MRSA). This preclinical testing was conducted through our collaboration with Linnaeus Bioscience Inc. Testing by Linnaeus Bioscience demonstrated that the MRSA and VRE pathogen strains and clinical isolates remained sensitive to several of our lantibiotic structures analyzed despite their resistance to so-called drugs of last resort such as oxacillin, methicillin, vancomycin and/or daptomycin. More than 2.8 million antibiotic-resistant infections occur in the U.S. each year, and more than 35,000 people die as a result. The results of our work with Linnaeus Bioscience advance our long-term mission to become a provider of treatments for infectious diseases. We remain committed to fighting infectious diseases through the development of our lantibiotics pipeline against MRSA and VRE pathogens.

Product Candidates

Through our wholly-owned subsidiary, NTI, we began the research and development stage for our new Terra CoV-2 and NT-CoV2-1 vaccine product candidates. We hold a nonexclusive, worldwide intellectual property license agreement for certain research, patent applications and biological materials relating to the use of pre-fusion coronavirus spike proteins for the development and commercialization of a vaccine against SARS-CoV-2. We also hold a non-exclusive license with the NRC that enables us to pursue the rapid development of next-generation vaccines against the SARS-CoV-2 (the “NIH License”) virus and its variants (the “NRC License” and together with the NIH License the “License Agreements”).

Additionally, we are developing semi-synthetic lantibiotic analogs that may be effective against systemic Gram-positive multidrug infections, and analogs that may be effective in treating Gram-negative infections. We seek to protect our product candidates through patents and patent applications pursuant to the terms of our License Agreements.

Product/Candidate	Description	Application	Status
NT-CoV2-1	Intranasal vaccine candidate (recombinant protein + adjuvant) to provide long lasting immunity against SARS-CoV-2	Broad, community-based vaccine immunity against SARS-CoV-2	Pre-clinical
Antibiotics	Semi-synthetic analogs of MU1140: Member of lantibiotic class of antibiotics	Healthcare-associated infections	Pre-clinical

Our Business Development Strategy

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

Financial Overview

Impact of the Novel Coronavirus.

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

To date, we and our development partners, have been able to conduct ordinary operations at or near normal levels and do not currently anticipate any interruptions for the foreseeable future. However, there could be additional repercussions for our operations, particularly for the initial development of our NT-CoV2-1 product candidate, including but not limited to, the sourcing of materials for product candidates, manufacture of supplies for preclinical and/or clinical studies, delays in clinical operations, which may include the availability or the continued availability of patients for trials due to such things as quarantines, conduct of patient monitoring and clinical trial data retrieval at investigational study sites. The continuation of the pandemic could adversely affect our planned clinical trial operations, including our ability to conduct the trials on the expected timelines and recruit and retain patients and principal

investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if their geography is impacted by the pandemic. Further, the COVID-19 pandemic could result in delays in our clinical trials due to prioritization of hospital resources toward the pandemic, the broad emergency use authorization of vaccines, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

Research and Development Expenses

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses consist primarily of employee-related expenses, which include salaries and benefits and attending science conferences; expenses incurred under our License Agreements with third parties and under other agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our nonclinical studies; the cost of acquiring and manufacturing clinical trial materials; facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, and depreciation of fixed assets; license fees, for and milestone payments related to, in-licensed products and technology; stock-based compensation expense; and costs associated with nonclinical activities and regulatory approvals. We expense research and development costs as incurred.

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

Our research and development expenses were $3,679,262 and $5,883,693 for the six-months ended June 30, 2023 and 2022, respectively. Our research and development costs are tracked by our COVID vaccine program and our lantibiotics program. Due to limited resources, while we continue our development efforts, we have focused on reducing our research and development expenses until we can raise additional capital.

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

Our plan is to budget and manage expenditures in research and development such that they are undertaken in a cost-effective manner yet still advance the research and development efforts. While we have some control under our Lantibiotic program and the License Agreements as to the planning and timing of our research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, overall research and development expenses could increase as a result of our vaccine product candidate. 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.

Recent Financing

On August 4, 2023, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with two healthcare-focused investors, pursuant to which the Company agreed to issue in a private placement (the "Offering"), an aggregate of (i) 404,728 shares of the Company's common stock, $0.001 par value (the "Common Stock"), and (ii) 404,728 shares of Series E Mirroring Preferred Stock (the "Series E Preferred Stock"), the rights and preferences of which are set forth in the Certificate of Designation filed with the Secretary of State for the State of Florida. The closing of the offering occurred on August 4, 2023. The gross proceeds from the offering were approximately $850,000. The Company intends to use the net proceeds from the offering for general corporate purposes.

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 are aware that certain general and administrative expenses could increase for, among others, the following reasons:

- the efforts we undertake from, time to time, to raise additional capital; and
- consulting, legal, accounting and investor relations costs associated with being a public company.

Other Income (Expense)

Other income (expense) includes miscellaneous income, 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

At December 31, 2022, the Company has federal and state tax net operating loss carryforwards of $150,083,903. Federal and state tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037 and are not subject to taxable income limitations. Federal tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but are subject to taxable income limitation pursuant to the Tax Cuts and Jobs Act that was enacted on December 22, 2017. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. The Company also has federal research and development tax credit carryforwards of $4,834,847. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2042 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 NTI, which may result in a change in ownership as defined by IRC Section 382, or could result in a change in control in the future. In each period since our inception, we have recorded a 100% valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal tax benefit in our statements of operations.

Results of Operations for the Three Months Ended June 2023 and 2022

Grant revenue. Grant revenue was $13,163 for the three months ended June 30, 2023 compared to $30,391 for the three months ended June 30, 2022, a decrease of $17,228 or 57%. This decrease was attributable to awards received for a small business innovation research grant that expired in the period subsequent to June 30, 2023.

Research and Development. Research and development expenses were $2,006,696 for the three months ended June 30, 2023 compared to $2,590,032 for the three months ended June 30, 2022, a decrease of $583,336 or 23%.

	For the Three Months Ended June 30, 2023	For the Three Months Ended June 30, 2022
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	214,214	297,520
COVID Vaccine Development Expense		
Clinical Research	513,056	864,367
Non-clinical research and development activities	1,279,426	1,428,145
Total Research and development activities	**$ 2,006,696**	**$ 2,590,032**

This decrease was mainly driven by approximately $0.5 million of decreased costs associated with the development of our COVID vaccine and primarily associated with costs for outside consultants. Additionally, there were decreases in research and development expense for our lantibiotic product of approximately $0.07 million. Decreases in expense related to the lantibiotic product were largely related to purchases of equipment in the comparable period in 2022 and decreased research and development activities in the comparable period of 2023.

General and Administrative. General and administrative expenses were $1,115,785 for the three months ended June 30, 2023 compared to $1,044,334 for three months ended June 30, 2022, a decrease of approximately $71,451 or 7% This decrease was primarily due to decreased expenses related to:

- Public company related expenses of approximately $0.03 million,
- Board of Director compensation related expense of $0.05 million, and
- Legal expenses of approximately $0.06 million, and
- Non-employee stock option and Insurance expense of approximately $0.08 million

These expense decreases were offset by increases in:

- Consultant expense for third party accounting support of approximately $0.07 million,
- Accounting expenses related to our 2022 financial restatements of approximately $0.2 million, and
- Rent expense of approximately $0.06 million.

Other Income (Expense). Other income, net was $58,732 for the three months ended June 30, 2023 compared to $14,432 for the three months ended June 30, 2022, resulting in an increase of $44,300 or 307%. The net change was primarily attributable to an increase in interest income of $43,585 or 284% for the three-month period ended June 30, 2023 compared to 2022.

Results of Operations for the Six Months Ended June 2023 and 2022

Grant revenue. Grant revenue was $30,187 for the six months ended June 30, 2023 compared to $45,474 for the six months ended June 30, 2022, a decrease of $15,287 or 34%. This decrease was attributable to awards received for a small business innovation research grant that expired in the period subsequent to June 30, 2023.

Research and Development. Research and development expenses were $3,679,272 for the six months ended June 30, 2023 compared to $5,883,693 for the six months ended June 30, 2022, a decrease of $2.2 million or 37%.

	For the Six Months Ended June 30, 2023	For the Six Months Ended June 30, 2022
Lantibiotics Expense		
Clinical Research	$ -	$ -

Non-clinical research and development activities	491,506	688,557
COVID Vaccine Development Expense		
Clinical Research	653,224	1,955,117
Non-clinical research and development activities	2,534,542	3,240,019
Total Research and development activities	**$ 3,679,272**	**$ 5,883,693**

This decrease was primarily due to approximately $2.0 million of decreased costs associated with the COVID vaccine development program. Additionally, decreases in research and development for the development of our lantibiotic product were reflected in salaries, wages and benefits, and other overhead expenses of approximately; $60,000, $25,000, and $100,000 respectively. The decrease in research and development expenses attributable to the vaccine development program reflect our actions toward the requisite steps to manage the timing of expenses associated with the preclinical efforts. The research and development expenses attributable to the vaccine development program related to activities necessary to be in a position to submit an Initial New Drug Application to the FDA or other regulatory agency, including conducting toxicology studies in mice, hamsters, and rabbits, enablement of COVID 19 variants, securing an adjuvant, assay testing, stability and release testing and preparing the elements necessary for manufacturing of our vaccine product candidate in order to be in a position to move forward with a Phase 1 and Phase 2 clinical studies.

General and Administrative. General and administrative expenses were $2,365,048 for the six months ended June 30, 2023 compared to $2,375,883 for six months ended June 30, 2022, a decrease of approximately $11,000 or 0.5% This decrease was primarily due to decreased expenses related to:

- Public company related expenses of approximately $0.3 million,
- Employee and non-employee related options expense of $0.2 million, and
- Other overhead related expenses for director compensation, travel, insurance, and supplies of approximately $0.1 million

These expense decreases were offset by increases in:

- Consultant expense for third party accounting support of approximately $0.2 million,
- Accounting expenses related to our 2022 financial restatements of approximately $0.2 million, and
- Other overhead related expenses for salaries and wages, legal, and rent expenses of approximately $0.2 million

Other Income (Expense) Other income, net was $118,710 for the six months ended June 30, 2023 compared to $33,566 for the six months ended June 30, 2022, resulting in an increase of $85,144 or 254%. The net change was primarily attributable to an increase in interest income of $93,880, for the six-month period ended June 30, 2023 compared to 2022.

Liquidity and Capital Resources

Since our inception, we have funded our operations primarily through the sale of equity securities in our initial public offering, the sale of equity securities and warrants in private placements, debt financing, warrant exercises, public offerings, and grants. During the six months ended June 30, 2023 and 2022 our operating activities used cash of $4,685,323, and $9,019,757, respectively. The decrease primarily resulted from our decrease in net losses adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of $6,957,573 and $12,675,299 at June 30, 2023 and December 31, 2022, respectively.

During the six months ended June 30, 2023 and 2022, our investing activities used cash of $0 and $75,047 respectively.

During the six months ended June 30, 2023 and 2022, our financing activities used cash of $267,640 and $303,416 respectively. The cash used by financing activities during the six months ended June 30, 2023, was primarily due to payments on short term notes payable related to financed insurance premiums.

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:

At-the-Market ("ATM Program")

On February 1, 2021, we entered into a Sales Agreement (the "Sales Agreement") with A.G.P./Alliance Global Partners, as sales agent (the "Sales Agent"), pursuant to which we may offer and sell through or to the Sales Agent shares of our Common Stock (the "ATM Program"). During the three months ended March 31, 2021, we issued an aggregate of 356,650 shares of Common Stock and received gross proceeds of an aggregate of approximately $27.8 million under our ATM Program. The ATM Program could be terminated 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.

On December 19, 2022, we sent written notice of termination to A.G.P./Alliance Global Partners ("AGP"), pursuant to the terms of our Sales Agreement with AGP in connection with the Company's ATM Program. The termination took effect on December 29, 2022.

On February 24, 2023 we entered into an ATM with Ladenburg Thalmann & Co. Inc ("Ladenburg") to sell shares of our common stock. The Company intends to use the proceeds from the ATM to continue funding its COVID Vaccine program and its lantibiotics program and for the general corporate purposes, including capital expenditures, working capital, and research and development activities. During the six-month period ended June 30, 2023 we did not issue any shares of common stock under our ATM program.

Other Financings

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

Products Liability Insurance

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

Directors' and Officers' Insurance

On August 5, 2022, we entered into a short-term note payable for $528,429 bearing interest at 6.24% to finance a portion of the directors' and officers' liability insurance and employment practices liability insurance premiums. Principal and interest payments on this note began August 24, 2022 and are made evenly based on a straight-line amortization over a 10-month period with the final payment being due on May 24, 2023.

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 were made evenly based on a straight-line amortization over a 10-month period with the final payment paid in May of 2022.

Recent Developments

On August 4, 2023, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with two healthcare-focused investors, pursuant to which the Company agreed to issue in a private placement (the "Offering"), an aggregate of (i) 404,728 shares of the Company's common stock, $0.001 par value (the "Common Stock"), and (ii) 404,728 shares of Series E Mirroring Preferred Stock (the "Series E Preferred Stock"), the rights and preferences of which are set forth in the Certificate of Designation filed with the Secretary of State for the State of Florida. The closing of the offering occurred on August 4, 2023. The gross proceeds from the offering were approximately $850,000. The Company intends to use the net proceeds from the offering for general corporate purposes.

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. On August 26, 2022, holders of 4,000,000 shares of the Company's Series A Convertible Preferred Stock, and 2,550,000 shares of the Company's Series B Convertible Preferred Stock converted the Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock into an aggregate of 15,167 shares of common stock. As of June 30, 2023 our 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	5,417,000	9,028
Series B Preferred	4,050,000	13,500

In addition, we issued warrants to purchase shares of Common Stock to the Series A holders, and to the Series B holders in connection with the Preferred Stock Financing. As of June 30, 2023, there are 11,828 and 11,720 shares of common stock able to be acquired upon exercise of the warrants held by our Series A and Series B holders respectively.

Except as otherwise required by law, the Series A and Series B Preferred Stock have no voting rights. However, as long as any shares of Series A and Series B Preferred Stock are outstanding, we shall not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A and Series B Preferred Stock, (a) alter or change adversely the powers, preferences or rights given to the Series A or Series B Preferred Stock or alter or amend the Certificate of Designation, (b) amend its articles of incorporation or other charter documents in any manner that adversely affects any rights of the holders of Series A and Series B Preferred Stock, (c) increase the number of authorized shares of Series A and Series B Preferred Stock, or (d) enter into any agreement with respect to any of the foregoing. Upon any liquidation, dissolution or winding-up by us, whether voluntary or involuntary that is not a Fundamental Transaction (as defined in the Certificate of Designations), the holders of Series A and Series B Preferred Stock shall be entitled to receive out of the assets, the greater of (i) the product of the number of shares of Series A and Series B Preferred Stock then held by such holder, multiplied by the Original Issue Price; and (ii) the amount that would be payable to such holder in the Liquidation (as defined in the Certificate of Designations) in respect of Common Stock issuable upon conversion of such shares of Series A and Series B Preferred Stock if all outstanding shares of Series A and Series B Preferred Stock were converted into Common Stock immediately prior to the Liquidation. The Series A and Series B Preferred Stock is classified as permanent equity. Each of the Series A and Series B Preferred Stock have redemption rights to the extent we have funds legally available therefore, at any time after the fifth anniversary of the original issue date of the applicable Series A and Series B Preferred Stock. We have the right to redeem all or any portion of the outstanding shares of Series A and Series B Preferred Stock at the original issue price by providing at least seventy-five (75) days written notice of such redemption to all holders of the then outstanding shares of Series A and Series B Convertible Preferred Stock.

Future Capital Requirements

Our capital requirements for the remainder of 2023 and the first half of 2024 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 product candidate and our success in pursuing strategic licensing and funded product development relationships with external partners. Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our technologies including continued increases in costs related to research, nonclinical testing and clinical trials, as well as costs associated with our capital raising efforts and being a public company. We will require substantial funds to conduct research and development and nonclinical and Phase 1 and Phase 2 clinical testing of our licensed, patented technologies and to develop sublicensing relationships for the Phase 2 and 3 clinical testing and manufacture and marketing of any products that are approved for commercial sale. Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents, provide us with limited liquidity. We believe our existing cash will allow us to fund our operating plan through the fourth quarter of 2023. As a result, we have implemented certain cost-saving initiatives, including reducing our efforts and staff focused on our lantibiotics program, which are expected to negatively impact the development of our lantibiotics program. See, "Risk Factors." We expect to manage the timing of our development expenditures and to continue to seek additional funding for our operations. Any such required additional capital may not be available on reasonable terms, if at all. If we were unable to obtain additional financing, we may be required to reduce the scope of, delay or eliminate some or all of our planned clinical testing, research and development and commercialization activities, which could harm our business. The sale of additional equity or debt securities may result in additional dilution to our shareholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We also will require additional capital beyond our currently forecasted amounts.

For example, as we seek to move forward with the development of NT-CoV2-1 vaccine candidate and our other product candidates, we will require additional capital. In addition, we continue to pursue other COVID-19 research and development funding opportunities through governmental and

nongovernmental sources, as well as potential research collaboration arrangements with academic institutions and other commercial partners. Our ability to advance the development of our NT-CoV2-1 vaccine candidate at our currently anticipated pace, in accordance with our License agreements, is dependent upon our ability to secure additional capital resources through these funding opportunities or an alternative capital raise, such as an equity or debt financing or other strategic business collaboration. Moreover, the global impact of COVID-19 could further impact our need for additional capital if we experience delays in our anticipated timelines or achievement milestones.

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

- conducting preclinical research for our NT-CoV2-1vaccine product candidate, filing an IND with the FDA and, if approved, engage in Phase 1 clinical trials;
- our ability to partner or collaborate with third parties;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to advance our lantibiotic development or achieve milestones under our License Agreements and the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amounts of sales of, or royalties on, our products and future products, if any.

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

Critical Accounting Estimates and Policies

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”). The preparation of consolidated financial statements in accordance with US GAAP requires us to make estimates and assumptions that affect reported amounts and related disclosures. We consider an accounting estimate to be critical if it requires assumptions to be made that were uncertain at the time the estimate was made; and changes in the estimate or different estimates that could have been made could have a material impact on our results of operations or financial condition. The principal area of estimation reflected in the consolidated financial statements are estimates for research and development expenses and related prepaid and accrued expenses, which are based on the percentage of completion of the Company’s contracts with Contract Research Organizations.

In April of 2023 management reviewed the terms and conditions of the Company’s research and development contracts and the payments; and concluded that during the three-month period ended March 31, 2022, three- and six-month periods ended June 30, 2022, and the three- and nine- month periods ended September 30, 2022 amounts were paid as part of a prepayment arrangement. Management reviewed Accounting Standards Codification Topic 730 Research and Development guidance related to recording initial upfront payments to vendors and determined that the unaudited consolidated financial statements originally reported for the stated periods classified research and development expense on the unaudited consolidated statement of operations that should be classified as prepaid expense on the Company’s unaudited consolidated balance sheet.

As a result, management, the Audit Committee and the Board of Directors concluded that the following financial statements should be restated and could no longer be relied upon.

i. The Company’s unaudited consolidated financial statements for the three-months ended March 31, 2022 included in the Company’s Quarterly Report of Form 10-Q, filed with the SEC on May 13, 2022 (the “Q1 2022 10-Q”); and

ii. The Company’s unaudited consolidated financial statements for the three and six-months ended June 30, 2022 included in the Company’s unaudited consolidated Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2022 (the “Q2 2022 10-Q”); and

iii. The Company’s unaudited consolidated financial statements for the three and nine-months ended September 30, 2022, included in the Company’s unaudited consolidated Quarterly Report on Form 10-Q filed with the SEC on November 14, 2022 (the “Q3 2022 10-Q”).

The Company determined that the reporting effects of the above errors had a material impact to the Company’s unaudited consolidated financial statements of the Company for the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q. As a result, the Company determined that the unaudited consolidated financial statements should be restated, and the Company should file an amendment to the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q with the SEC. All such amendments were filed with the SEC on April 14, 2023.

As a result there have been changes to our critical accounting estimates related to research and development expense and initial upfront payments. For a detailed discussion of our critical accounting estimates, see our Annual Report on Form 10-K for the year ended December 31, 2022.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the six months ended June 30, 2023 that have had or are expected to have an impact on our consolidated financial statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Management's evaluation of the effectiveness of the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act was performed under the supervision and participation of our senior management, including our Principal Executive Officer and President and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to management, including our Principal Executive Officer and President and Chief Financial Officer, to allow timely decisions regarding required disclosures.

On April 4, 2023, the Principal Executive Officer and President, Chief Financial Officer, Audit Committee, and Board of Directors concluded that the following financial statements should be restated and could no longer be relied upon.

i. The Company's unaudited consolidated financial statements for the three months ended March 31, 2022 included in the Company's Quarterly Report of Form 10-Q, filed with the SEC on May 13, 2022 (the "Q1 2022 10-Q"); and

ii. The Company's unaudited consolidated financial statements for the three and six-months ended June 30, 2022 included in the Company's unaudited consolidated Quarterly Report on Form 10-Q, filed with the SEC on August 9, 2022 (the "Q2 2022 10-Q"); and

iii. The Company's unaudited consolidated financial statements for the three and nine-months ended September 30, 2022, included in the Company's unaudited consolidated Quarterly Report on Form 10-Q filed with the SEC on November 14, 2022 (the "Q3 2022 10-Q").

The following errors impacted such filings: (i) not properly analyzing research and development contracts .

Management reviewed the terms and conditions of the research and development contracts and the payments and concluded that during the three-month period ended March 31, 2022, three- and six-month periods ended June 30, 2022, and the three- and nine- month periods ended September 30, 2022 amounts were paid as part of a prepayment arrangement. Management reviewed Accounting Standards Codification Topic 730 Research and Development guidance related to recording initial upfront payments to vendors and determined that the unaudited consolidated financial statements originally reported for the stated periods classified research and development expense on the unaudited consolidated statement of operations that should be classified as prepaid expense on the Company's unaudited consolidated balance sheet.

The Company determined that the reporting effects of the above errors had a material impact to the Company's unaudited consolidated financial statements of the Company for the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q. As a result, the Company determined that the unaudited consolidated financial statements should be restated, and the Company should file an amendment to the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q with the SEC. All such amendments were filed with the SEC on April 14, 2023.

As a result, we have concluded that there is a material weakness related to the review of research and development contracts and determined that our disclosure controls and procedures and internal control over financial reporting were not effective. Under Public Company Accounting Oversight Board standards, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a misstatement of our consolidated annual or interim financial statements will not be prevented or detected on a timely basis. The existence of this issue could adversely affect us, our reputation or investor perceptions of us. We will take measures to remediate the underlying cause of the material weakness noted above. As we continue to evaluate and work to remediate the material weakness, we may determine to take additional measures to address the control deficiencies.

Although we plan to complete this remediation process as quickly as possible, we cannot provide any assurance as to when the remediation process will be complete, and our measures may not prove to be successful in remediating the material weakness. If our remedial measures are insufficient to address the material weakness, or if additional material weaknesses or significant deficiencies in our internal control over financial reporting are discovered or occur in the future, our consolidated financial statements may contain misstatements and we could be required to restate our financial results. In addition, if we are unable to successfully remediate the material weakness or if we are unable to produce accurate consolidated financial statements in the future, our stock price, liquidity and access to the capital markets may be adversely affected and we may be unable to maintain compliance with applicable stock exchange listing requirements. Further, because of its inherent limitations, even our remediated and effective internal control over financial reporting may not prevent or detect all misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in our conditions, or that the degree of compliance with our policies or procedures may deteriorate.

Changes in Internal Controls over Financial Reporting

Our management, with the participation of our Chief Executive Officer, President, and Chief Financial Officer, has concluded there were no other 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.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting. We will continue to monitor and assess the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and President, 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, 2022 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, 2022 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, 2022 filed on April 17, 2023. 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 $5.9 million and $8.2 million for the six months ended June 30, 2023 and 2022, respectively, and approximately $14.3 million for the year ended December 31, 2022. As of June 30, 2023, our accumulated deficit was approximately $191.5 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our plans to begin preclinical research, contract manufacturing and file an IND for our NT-CoV2-1 vaccine product candidate and the research and development of our product candidates in the area of lantibiotics ("Lantibiotics Program") will continue and, to have successful results, likely will require an increase in the level of our overall expenses going forward. 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. Our current cash, cash equivalents ad short-term investments are not sufficient to fully implement our business strategy and sustain our operations. As a result of our limited resources, we have undertaken cost-saving initiatives, including reducing our efforts and staff focused on our lantibiotics program. Our actual costs may ultimately vary from our current expectation, 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. 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. Due to of our accumulated losses and substantial doubt that we can continue as a going concern beyond December 2023, the Company is evaluating various opportunities for its Lantibiotics Program and its N-CoV2-1 vaccine product candidate, as well as alternative assets that could be acquired or developed. These opportunities could include a wide range of options including, among other things, a potential sale, spin-off, fund raising, combination or other strategic transaction, which may also include the winding down of research and development activities. The result of this process may result in the liquidation of assets for significantly less than amounts that have been invested in them, the write-off of prior expenses incurred in connection with the development of such assets and may have a material adverse effect on our results of operations and liquidity. Notwithstanding the above, the Company will seek to maximize the value of such assets to the extent possible. 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 believe our existing cash will allow us to fund our operating plan only through the fourth quarter of 2023.

ITEM 2. UNREGISTERED SALE OF EQUITY SECURITIES, USE OF PROCEEDS AND ISSURER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.4	6/26/18	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.5	2/28//22	
3.6	Bylaws	SB-2	333-100568	3.2	10/16/02	

3.7	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.8	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.9	Third Amendment to Bylaws	8-K	001-32188	3.9	2/28/22	
3.10	Certificate of Designation	8-K		3.1	8/7/23	
3.11	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K		3.1	1/23/23	
10.1	National Research Council (NRC) Canada Technology License Agreement (dated July 26, 2021) and Amendment One (dated September 2, 2021).	10-Q	001-32188	10.0	11/15/21	
10.2	NRC Technology License Amendment 2	10-K	001-32188	10.6	3/24/22	
10.3	NRC Technology License Amendment 3	10-K	001-32188	10.7	3/24/22	
10.4	NRC Technology License Amendment 4	10-Q		10.4	8/9/22	
10.5	NRC Technology License Amendment 5 (dated April 3, 2023)*	10-Q		10.7	5/12/23	
10.6	Three-Way Collaborative Research Agreement*	10-Q				X
10.7	Form of Securities Purchase Agreement	8-K		10.1	8/7/23	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X

101.INS	Inline XBRL Instance Document

101.SCH	Inline XBRL Taxonomy Extension Schema	X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase	X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase	X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase	X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase	X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document	

*Portions of the exhibits have been omitted pursuant to Item 601(b)(10)(iv).

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 11th day of August 2023.

ORAGENICS, INC.

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

BY: */s/ Janet Huffman*
Janet Huffman, Chief Financial Officer and Principal Accounting Officer

Exhibit 10.6

[***] 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.

SYNERGIQC NETWORK AND RESEARCH FUNDING AGREEMENT

THIS AGREEMENT (the "**Agreement**") is made and entered into:

BY AND BETWEEN: **NATIONAL RESEARCH COUNCIL CANADA,** a departmental corporation of the Government of Canada, whose head office address is 1200 Montreal Road, Ottawa, Ontario K1A 0R6 Canada;

(hereinafter referred to as "**NRC**" or as a "**Research Entity**" or the "**Lead Research Entity**")

AND: **INSPIREVAX INC.**, a corporation duly constituted under the laws of **Quebec**, having its head office at 46 rue de Saint-Tropez, Kirkland, Quebec H9J 2K6 Canada;

(hereinafter referred to as **"Inspirevax"**)

AND: **ORAGENICS INC.**, a corporation duly constituted under the laws of the state of **Florida, United States**, having its head office at 4902 Eisenhower Boulevard – Suite 125- Tampa, Florida 33634, U.S.A.;

(hereinafter referred to as "**Oragenics**")

(each of **Inspirevax** and **Oragenics** may hereinafter be referred to individually as a "**Co-Funder**" and may collectively be referred to as the "**Co-Funders**")

AND: **CQDM - CONSORTIUM QUÉBÉCOIS SUR LA DÉCOUVERTE DU MÉDICAMENT (FÉDÉRAL)**, a not-for-profit corporation duly constituted and governed by the Canada Not-for-profit Corporations Act, having its registered office at 630 René-Lévesque Boulevard West, 20th floor, Montréal, Québec, Canada, H3B 1S6;

(hereinafter referred to as "**CQDM**")

(each of **Inspirevax, Oragenics** and **CQDM** may hereinafter be referred to individually as a "**Funder**" and may collectively be referred to as the "**Funders**")

(each of **NRC**, **Inspirevax** and **Oragenics** and **CQDM**, hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**")

PREAMBLE

WHEREAS CQDM is a not-for-profit organization created to promote, stimulate and support drug research, development and discovery and, accordingly, to fund and manage the fulfilment of innovative research projects aimed at developing tools, enabling technologies, or new drug candidates that facilitate and accelerate the drug discovery and development process;

WHEREAS Inspirevax is a company pursuing the development of mucosal adjuvants for use in vaccines and immunotherapies administered by the intranasal route;

WHEREAS Oragenics is a development-stage company dedicated to fighting infectious diseases, including those caused by coronaviruses and multidrug-resistant organisms**;**

WHEREAS NRC is a public institution and accordingly its services to be rendered hereunder are exonerated from applicable taxes;

WHEREAS the Project Summary attached hereto, the Contract Documentation identified therein and the intervention(s) of the Investigator(s) attached hereto form an integral part of this Agreement and all capitalized terms used herein are defined in the Project Summary and Contract Documentation;

WHEREAS in case of earlier start of the Project, the Research Entity(ies) and Co-Funder(s) acknowledge that they have been informed in due time and understood that this Agreement would apply and govern retroactively as if signed on such earlier start date indicated in the Project Summary, as applicable, unless indicated otherwise in this Agreement;

WHEREAS the Co-Funder(s) and the Third-Party Funder(s) (if any) selected the Project for funding, and the Research Entity(ies) agree(s) to perform the Project in accordance with this Agreement;

NOW THEREFORE, in consideration of the foregoing premises, the Parties have caused their duly authorized representatives to sign this Agreement as of **May 29 2023**:

NATIONAL RESEARCH COUNCIL CANADA

/s/ Lakshmi Krishnan

Name: Lakshmi Krishnan
Title: VP Life Sciences

CQDM - CONSORTIUM QUÉBÉCOIS SUR LA DÉCOUVERTE DU MÉDICAMENT (FÉDÉRAL)

/s/ Diane Gosselin

Name: Diane Gosselin
Title: President and CEO

INSPIREVAX INC.

/s/ Joseph Zimmerman

Name: Joseph Zimmerman
Title: President & CEO

ORAGENICS INC.

/s/ Kimberly Murphy

Name: Kimberly Murphy
Title: President &CEO

INTERVENTIONS

The undersigned, being a Principal Investigator or Co-Investigator, having read and understood this Agreement, hereby agrees to be bound by the obligations of the Principal Investigator or Co- Investigator, whichever applies, to act in accordance with all the terms and conditions of this Agreement.

In addition, by accepting funding from the Granting Agency(ies) through CQDM, the undersigned understand that maintaining public trust in the integrity of researchers is fundamental to building a knowledge-based society and they affirm that they have read and they agree to conduct the Project in accordance with (i) internal ethical principles in force in concerned Research Entity, the principles established in the Tri-Council Policy Statement (available at: https://ethics.gc.ca/eng/tcps2-eptc2_2018_chapter3-chapitre3.html) and other applicable scientific, ethical and professional standards regulation, guidance and laws namely as it relates to ethical review, consent process, confidentiality and privacy; (ii) Granting Agency(ies) Policies and Guidelines (available at: https://science.gc.ca/eic/site/063.nsf/eng/h_1E7A5F18.html); (iii) the Agreement and, when applicable, (iv) terms and conditions set forth by the Third-Party Funder(s).

Principal Investigator

The NRC Principal Investigator's participation, work and compliance with the Project governed by the NRFA Agreement is committed and confirmed by the signature of the person authorized to sign on behalf of NRC on the signature page.

Name: Yves Durocher
Date: NA

Co-Investigator(s)

The NRC Co-Investigator's participation, work and compliance with the Project governed by the NRFA Agreement is committed and confirmed by the signature of the person authorized to sign on behalf of NRC on the signature page.

Name: Matthew Stuible
Date: NA

(End of signatures)

PROJECT SUMMARY

Project title:	**Development of a Variant-Agnostic COVID-19 Protein Antigen Candidate for a Multivariant Intranasal Vaccine**	
CQDM Program:	**SynergiQc**	
Project scheduled start and Completion Date:	**October 1, 2022**	**December 31, 2024**
Lead Research Entity and Principal Investigator:	**NRC**	**Dr. Yves Durocher**
Other Research Entities and Co-Investigators:	**NRC**	**Dr. Matthew Stuible**
Research Entity(ies) notice information:	**NATIONAL RESEARCH COUNCIL CANADA** Attention: Dr Yves Durocher, Project Leader 6100 Royalmount Avenue, Montreal, Quebec H4P 2R2 Canada Email: yves.durocher@nrc-cnrc.gc.ca	
Funder(s) notice information:	**CQDM - CONSORTIUM QUÉBÉCOIS SUR LA DÉCOUVERTE DU MÉDICAMENT** E-mail: contracts@cqdm.org Attention: the CQDM President **INSPIREVAX INC.** **Joseph Zimmermann**, CEO 46 rue de Saint-Tropez, Kirkland, Quebec H9J 2K6 Canada Email: joseph@inspirevax.com **ORAGENICS INC.** **Janet Huffman,** Chief Financial Officer 4902 Eisenhower Boulevard, Suite 125 Tampa, Florida 33634 U.S.A. Email: jhuffman@oragenics.com	

Funds Manager:	**NATIONAL RESEARCH COUNCIL CANADA**

REPORTING

Financial Reports:	Reports to be provided: (a) Semi-annual financial reports as of March 31st and September 30th of each year during the Term within thirty (30) days; (b) a final consolidation report for the Project signed by the authorized representative of each Research Entity within thirty (30) days after the Completion Date or upon termination of this Agreement;
Scientific Reports:	Reports to be provided: (a) Semi-annual scientific reports as of March 31st and September 30th of each year during the Term within (30) days; (b) a final scientific report within thirty (30) days after the Completion Date or upon termination of this Agreement;
Other Reports:	(a) Key Performance Indicators (KPI) report as of March 31st of each year during the Term within thirty (30) days; (b) End of project satisfaction and outcome report; (c) Longitudinal reports on project outcomes (to be completed for a minimum of 5 years after the Term).

CONTRACT DOCUMENTATION	**REFERENCE**	
This Project Summary	-	
Project Executive Summary	Attached as Schedule 1	
Milestones & Deliverables	Attached as Schedule 2(A)	
Gantt Chart	Attached as Schedule 2(B)	
Funding Structure	Attached as Schedule 2(C)	
Budget	Attached as Schedule 2(D)	
Payment Schedule	Attached as Schedule 2(E)	
General Terms & Conditions	Attached as Schedule 3	
Rules established by the Government of Québec concerning eligible expenses including related travel	Attached as Schedule 4	
IP Management and Commercialization Agreement	Attached as schedule 5 ☒	Not app. ☐
Special terms & conditions	Attached as schedule 6 ☐	Not app. ☒

SCHEDULE 1
PROJECT EXECUTIVE SUMMARY

Challenge: As the global SARS-CoV-2 situation continues to evolve, the strategy of focusing vaccine development on the currently dominant variant of concern should be complemented by approaches that provide more durable and wider protection against future emerging variants that can be quickly manufactured for urgent deployment.

Solution: We believe that a spike antigen or mixture of antigens, possibly based in part on zoonotic virus sequences, could be designed as a booster for individuals already immunized with current SARS-CoV-2 vaccines to provide better protection against emerging variants with yet unknown spike sequences. Leveraging the NRC expertise in production, characterization and pre-clinical evaluation of recombinant spike proteins as candidate subunit vaccine antigens, the proposed project will support development of an intranasal COVID-19 vaccine that induces an optimal pan-variant antibody response. A diverse set of recombinant zoonotic spike proteins, chimeric and stabilized constructs that will be designed de novo based on well-established protein engineering approaches will be screened initially. These proteins will be used as booster doses in mice primed with 2 doses of a reference-strain SARS-CoV-2 spike-based vaccine and mice sera will be profiled for antibody specificity against a range of SARS-CoV-2 variants. In subsequent stages of the project, iterative protein engineering, CHO cell line development and in vivo experiments will be performed to narrow down the number of candidates and refine dosing and antigen combination strategies. A research cell bank (RCB) readily amenable to Master Cell Bank (MCB) generation that eventually would be used for clinical trials will also be created to ensure a rapid manufacturing in response to the emergence of new SARS-CoV-2 variants.

Expected Achievements/Impact: Ultimately, the project will deliver two to four well- characterized stable CHO pools (RCBs) expressing vaccine antigens with well-established preclinical efficacy (using intranasal immunization). These 2-4 novel antigens will be rapidly deployable to generate MCBs and Drug Substance (DS) using a de-risked, scaled manufacturing platform (developed already for the reference strain spike antigens) for clinical trials, enabling an efficient, informed response to future variants of concern. A corresponding set of analytical methods to characterize these antigens will be created in parallel as part of this proposal to facilitate the rapid scale up.

SCHEDULE 2(A)
MILESTONES & DELIVERABLES

MILESTONES

[***]

DELIVERABLES

[***]

SCHEDULE 2(B)
GANTT CHART

[***]

SCHEDULE 2(C)
FUNDING STRUCTURE

[***]

SCHEDULE 2(D)
BUDGET

[***]

SCHEDULE 2(E)

PAYMENT SCHEDULE

[***]

SCHEDULE 3
GENERAL TERMS & CONDITIONS

[See attached document]

SYNERGIQC GENERAL TERMS & CONDITIONS

1. DEFINITIONS

In the Agreement, the following terms shall have the following meaning:

"**Administrative Fee**" means the non reimbursable fee set forth in the Funding Structure payable to CQDM upon execution of the Agreement or as otherwise agreed to in the Payment Schedule in consideration of the enabling support offered by CQDM hereunder, in accordance with the requirements of the Granting Agency(ies);

"**Agreement**" means the Network and Research Funding Agreement, the Project Summary, the Contract Documentation identified therein and the intervention(s) of the Investigator(s);

"**Budget**" means the corresponding schedule included in the Contract Documentation;

"**Co-Investigator(s)**" means the person(s) identified as such in the Project Summary or the person(s) intervening as such to the Agreement, who shall manage the research team members within each Research Entity under the coordination of the Principal Investigator;

"**Completion Date**" means the completion date set forth in the Project Summary which shall not exceed thirty-six (36) months;

"**Confidential Information**" means all confidential information disclosed by a Party (referred to in this capacity as the " **Provider**") to another Party (referred to in this capacity as the "**Recipient**") including, without limitation, the terms and conditions of the Agreement and any confidential and/or proprietary information and documents relating to (i) the Project, including without limitation, all data, trade secrets, know-how and other proprietary information relating thereto and their related conception, development, use, modification and manufacturing, (ii) the Provider's business, finances, operations, research and development activities, products or services; and (iii) all other information which is not generally known to the public or is by its nature or the circumstances in which it is made available to the Recipient, is such that it would generally be considered confidential or proprietary. Without limiting the generality of the foregoing, Confidential Information includes, without limitation, all forms of Confidential Information and support containing Confidential Information, whether oral, written or digital, whether provided, disclosed, furnished or prepared before, on or after the Effective Date of the Agreement, including all analyses, compilations, data, studies, notes, reports or other documents prepared by or for the Provider, based upon or including any of such Confidential Information and, in all cases, shall include all

copies and tangible or intangible embodiments thereof, in whatever form or medium. However, Confidential Information shall not include the information that (i) is already known to the Recipient; (ii) after disclosure, became part of the public domain otherwise than through the fault of the Recipient; (iii) was in the possession of the Recipient at the time of disclosure and was not acquired, directly or indirectly, from the Provider under an obligation of confidentiality; or (iv) was received by the Recipient on a non-confidential basis from a third party, provided that such third party is not known by the Recipient to be bound by a confidentiality agreement with or other obligation of secrecy to the Provider.

"**Contract Documentation**" means the Project Proposal submitted to CQDM and the documents identified as such in the Project Summary which are hereby incorporated by reference in the Agreement;

"**Co-Funder(s)**" means the Party(ies) entering as such into the Agreement (if any);

"**CQDM Funds**" means the CQDM Funds set forth in the Funding Structure to be disbursed by CQDM to co-fund Eligible Expenses of the Project in accordance with the Agreement, which includes funds received from the Granting Agency(ies);

"**Deliverables**" means the deliverables of the Project described in the corresponding schedule included in the Contract Documentation;

"**Effective Date**" means the earlier of (i) the execution date of the Agreement specified at the beginning of the signature block; or (ii) the anticipated project start date specified in the Project Summary, if any, and upon which the Agreement becomes effective.;

SYNERGIQC GENERAL TERMS & CONDITIONS

"**Eligible Expenses**" means the expenses described in the Budget and made by the Research Entity(ies) in compliance with eligible expenses and travelling rules and other Granting Agency(ies) Policies and Guidelines as updated and supplemented by the Granting Agency(ies) from time to time;

"**Funders**" means collectively CQDM and the Co-Funder(s) (if any) and " **Funder**" means any of them;

"**Funding Structure**" means the corresponding schedule included in the Contract Documentation describing the CQDM Funds, the Matching Funds and the Administrative and annual membership fees, as applicable;

"**Funds**" means, collectively, the CQDM Funds and the Matching Funds;

"**Funds Manager**" means the sole Research Entity, when only one Research Entity enters into the Agreement, or the Research Entity identified as such in the Project Summary when multiple Research Entities enter into the Agreement, as applicable;

"**General terms & conditions**" means these general terms & conditions;

"**Granting Agency(ies)**" means governments and governments agencies which have financially contributed to the CQDM Funds, which includes the *Ministère de l'Économie, de l'Innovation et de l'Énergie* of the Government of Québec ("MEIE");

"**Granting Agency(ies) Policies and Guidelines**" means rules established by the Granting Agency(ies) as updated from time to time;

"**IP Management and Commercialization Agreement**" means the agreement referred to in section 8 of these General terms & conditions and attached under corresponding schedule included in the Contract Documentation;

"Investigator(s)" means collectively the Principal Investigator(s) and the Co-Investigator(s) (if any) and " **Investigator**" means any of them;

"**Lead Research Entity**" means the Research Entity identified as such in the Project Summary when multiple Research Entities enter into the Agreement or the sole Research Entity when only one Research Entity enters into the Agreement, as applicable;

"**Liability**" or "**Liabilities**" means any losses, damages, fines, costs, liabilities and expenses (including the reasonable fees, costs and expenses of attorneys and expert and court costs), to be paid further to a court order or settlement based on a claim for any civil, criminal, statutory or regulatory liability;

"**Matching Funds**" means the funds set forth in the Funding Structure and payable by the Co- Funder(s) (if any) and the Third-Party Funder(s) (if any) to co-fund the Project with CQDM as detailed in the Payment Schedule;

"**Milestones**" means the milestones described in the corresponding schedule included in the Contract Documentation;

"**Parties**" means collectively CQDM, the Co-Funder(s) (if any) and the Research Entity(ies) and " **Party**" means any of them;

"**Payment Schedule**" means the corresponding schedule included in the Contract Documentation;

"**Principal Investigator(s)**" means the person(s) identified as such in the Project Summary or the person(s) intervening as such to the Agreement, who shall manage the Project in accordancewith the Agreement;

"**Project**" means the research project presented in the Project Proposal and as identified, amended and supplemented by the Agreement, including, for clarity, the Funding Structure, the Milestones, the Deliverables, the Gantt Chart, the Budget and the Payment Schedule;

"**Project Proposal**" means the proposal and supplement and amendments thereto, if any, provided to CQDM to apply for funding of the Project;

"**Project Summary**" means the corresponding schedule included in the Contract Documentation;

"**Reports**" means the reports listed in the Project Summary to be completed by the Research Entity(ies) in forms provided by CQDM or as otherwise indicated by CQDM from time to time;

"**Research Entity(ies)**" means the Party(ies) entering as such into the Agreement; " **Term**" has the meaning set out in section 12 of these General terms & conditions;

"**Third-Party Fund(s)**" means (if any) the portion of the Matching Funds set forth in the Funding Structure payable by Third-Party Funder(s) as detailed in the Payment Schedule; and

"**Third-Party Funder(s)"** means (if any) the entity(ies) identified as such in the Funding Structure and that is/are not a party to the Agreement.

2. NETWORK

In consideration of performing a Project co-funded by CQDM, and provided that the Research Entity(ies) and the Co-Funder(s) are not in default hereunder, each Research Entity and Co- Funder(s) shall be or become, as soon as practically possible following the Effective Date, a member of CQDM of a class of membership to be determined by CQDM, pay the annual membership fees as determined by CQDM and become part of the network created by CQDM's activities.

3. PROJECT

The Research Entity(ies) and the Investigator(s) undertake to:

3.1 use best efforts to duly achieve the Project including the Milestones and the Deliverables within established timelines;

3.2 promptly inform CQDM of any event which may have a material impact on the Project and obtain prior written approval from all Parties before (i) making any change to the Milestones, Budget and/or Deliverables; or (ii) making any material change to the Project;

3.3 promptly provide Reports within established timelines;

3.4 conduct the Project in accordance with (i) internal ethical principles in force in concerned Research Entity, the principles established in the Tri-Council Policy Statement (available at: https://ethics.gc.ca/eng/tcps2-eptc2_2022_chapter3-chapitre3.html) and other applicable scientific, ethical and professional standards regulation, guidance and laws namely as it relates to ethical review, consent process, confidentiality and privacy; (ii) Granting Agency(ies) Policies and Guidelines; (iii) the Agreement and, when applicable, (iv) terms and conditions set forth by the Third-Party Funder(s);

3.5 obtain all appropriate rights, certifications, consents, permits and/or required ethical board approvals in due time to timely perform and complete the Project and provide copies thereof upon request;

3.6 abide by the internal policies and the principles established by the Granting Agency(ies) on conflict of interests and avoid any potential or actual conflict of interests in the conduct of the Project and where any such conflict of interest either arises or exists, disclose it promptly and manage it by taking such steps or by putting such measures in place as appropriate or as may be required by CQDM;

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3.7 maintain effective, complete and accurate written records of the experiments and other forms of work carried out in connection with the Project; and

3.8 abide by the internal procurement policy in place adopted by the applicable Research Entity, and proceed by way of tendering when applicable, for all expenses related to the purchase of goods and service required for the performance of the Project or construction work with an expenditure equal to or greater than the minimum threshold under the *Act respecting contracting by public bodies* (RLRQ, Chapter C-65.1).

4. FUNDS

4.1 Funders will disburse their respective Funds to the Research Entity(ies) in accordance with the Payment Schedule subject to each of the Research Entities duly carrying out, performing and completing each of its obligations under the Agreement.

4.2 Disbursements of CQDM Funds are further subject to (i) timely payment of the Administrative Fee to CQDM; (ii) fulfillment of any condition(s) imposed by the selection committee and/or Granting Agency(ies), as applicable; (iii) the achievement of the milestones and deliverables planned in the reference period; (iv) confirmation by the Research Entity(ies) of receipt of corresponding Matching Funds and in-kind contribution (if any); and (v) receipt of corresponding funds by CQDM from the Granting Agency(ies).

4.3 Final payment of the CQDM Funds will be adjusted so that all disbursements made to the Research Entity(ies) for the performance of the Project balance with the actual Eligible Expenses reported by the Research Entity(ies).

4.4 CQDM Funds cannot be exceeded and can be spent strictly for Eligible Expenses required to perform the Project in accordance with the Agreement before the Completion Date.

4.5 Disbursement(s) of CQDM Funds are subject to applicable taxes, including GST and QST. Depending on its tax status a Research Entity could be exonerated from such applicable taxes. When applicable according to its tax status, the Research Entity shall remit taxes and make the required declarations to the appropriate government authority. Accordingly, the Research Entity shall provide its QST and GST numbers in the Budget prior to the first disbursement and advise the Funders of any change thereof during the term of the Agreement. All costs to a Research Entity in relation with taxes shall be assumed by said Research Entity.

4.6 CQDM will disburse contribution to academic Research Entity(ies)' indirect costs of research determined by Granting Agency(ies), if any, as detailed in the Payment Schedule. Research Entity(ies) is/are responsible to obtain and collect indirect costs of research from Co-Funder(s) (if any) and/or Third-Party Funder(s) (if any) in accordance with Granting Agency(ies) Policies and Guidelines, as applicable.

4.7 The CQDM Funds are subject to appropriation of sufficient funds by the Granting Agency(ies) and approval of their respective treasury boards and continued receipt of contributions from Granting Agency(ies). The Research Entity(ies) acknowledge(s) that CQDM is not and shall not be held responsible for failure or delay of the Granting Agency(ies) to disburse corresponding funds to CQDM. The Research Entity(ies) further acknowledge(s) and agree(s) that CQDM is not and shall not be held responsible for failure or delay of Co- Funder(s) (if any) and Third-Party Funder(s) (if any) to disburse the Matching Funds.

5. BOOKS AND RECORDS

5.1 The Research Entity(ies) will maintain accurate and separate records and accounts of all expenses made in connection with the Project in accordance with generally accepted accounting principles, consistently applied, in such a way that the Funds are properly managed and protected in accordance with the Agreement and show descriptions and book values of all transactions involving the Funds. The Research Entity(ies) will maintain adequate financial controls at all times and follow specific financial controls that may be requested by CQDM. Such records and accounts shall be kept for at least seven (7) years from the Effective Date.

5.2 The Research Entity(ies) will provide, within a reasonable delay, copies of such records and accounts to the Granting Agency(ies) and CQDM upon request and will allow periodical visits (or online audits if visits are not allowed in the Research Entity(ies)) by representatives of the Granting Agency(ies) and CQDM during regular business hours (1 visit by bi-annual reporting period) upon prior notice of at least ten (10) business days to (i) assess compliance of the Research Entity(ies) with the Agreement; and (ii) review Funds expenditures to ensure that these were made in accordance with the Agreement. The Research Entity(ies) shall reasonably and to the extent permitted by any applicable law, collaborate with representatives of the Granting Agency(ies) and/or CQDM in any such audit process.

6. REPORTING

The Research Entity(ies) will provide Reports to CQDM at the frequency and within timelines set forth in the Project Summary and other information reasonably required by CQDM and the Co- Funder(s) (if any) from time to time. CQDM is hereby expressly authorized to share these Reports and other information with the Co-Funder(s) and Third-Party Funder(s) (if any) and the Granting Agency(ies).

7. LEADS & FUNDS MANAGER

7.1 When multiple Research Entities are involved, the Lead Research Entity will, for the purposes of the Agreement (i) serve as the main contact for the Research Entity(ies) and liaise with CQDM on behalf of the Research Entity(ies); (ii) obtain required consents and signatures from the Research Entities, as applicable; (iii) provide Reports and other information reasonably required by the Funder(s) and (iv) act as the Funds Manager unless another Research Entity is appointed to act as Funds Manager in the Project Summary.

7.2 Appointment of a Lead Research Entity does not affect the rights, obligations and responsibilities of the other Research Entity(ies) under the Agreement. The other Research Entity(ies) must collaborate with the Lead Research Entity at all times. For clarity, the Lead Research Entity has no authority to bind the other Parties and shall not be responsible or liable by the mere fact that it is the Lead Recipient for any failure by any Research Entity to comply with the obligations set forth herein.

7.3 When multiple Research Entities are involved, the CQDM Funds will be disbursed to the Funds Manager. The Funds Manager shall promptly redistribute CQDM Funds received to the Research Entity(ies) in accordance with the Budget.

8. RESULTS AND INTELLECTUAL PROPERTY

8.1 The Research Entity(ies) and the Co-Funder(s), as applicable, will agree on ownership and management of the results of the Project, as well as the commercialization and the exploitation rights thereof, restrictions on publications and applicable procedures in a separate agreement(the "**IP Management and Commercialization Agreement**").

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8.2 The IP Management and Commercialization Agreement and amendments thereto, if any, shall comply with the letter and spirit of the rules and policies established by the Granting Agency(ies) Policies and Guidelines that encourages and facilitates commercialization as promoted by the Granting Agency(ies). Copies of amendment(s) to the IP Management and Commercialization Agreement, if any, shall be provided to CQDM promptly to allow assessment of impact of such amendment(s) on the Project.

9. CONFIDENTIAL INFORMATION

9.1 The Parties will, from time to time, disclose Confidential Information to each other under the Agreement. Such Confidential Information exchanged between the Parties and the Investigator(s) shall be kept confidential and not be disclosed to anyone outside the Parties and Investigator(s). Notwithstanding the foregoing, certain relevant Confidential Information may be disclosed to person with a "need to know" basis for the purpose of the Agreement such as employees, students, and consultants or to actual or potential partners such as a société de valorisation, potential or actual licensee or business partners, actual or potential lenders or investors or potential acquirer or by CQDM to actual or potential Co-Funder(s) or Third-Party Funder(s); provided, however, that such receiving parties are bound by confidentiality obligations consistent with this section. The Confidential Information shall be used by the other Parties strictly in connection with the execution of their obligations and their rights hereunder. The obligations and undertakings under this section shall remain in force and survive for as long as Confidential Information remain confidential.

9.2 In the event that the Recipient becomes legally compelled to disclose all or part of the Confidential Information, the Recipient shall notify the Provider and collaborate in order to prevent or limit the disclosure or obtain any appropriate protective order or measure. In the event that disclosure may not be prevented, that the protective order or other measure is not obtained or that the Provider waives compliance with this provision, the Recipient shall disclose only that portion of the Confidential Information which is required in accordance with applicable law.

10. DISCLOSURE, ACKNOWLEDGEMENTS AND USE OF NAMES

10.1 Any press release and public disclosures by a Party concerning the Project is subject to the prior written consent of the other Party(ies), which consent shall not be unreasonably withheld or delayed. Parties however hereby expressly consent to public announcement of the Project, by way of a press release or otherwise, by CQDM and the Granting Agency(ies) and further allow them to make the following information a matter of public record by way of prints, websites, social networks or otherwise: name and department of Investigator(s), the Parties' names, Project title, Project duration and Project value and non-confidential scientific summary of the Project provided to CQDM by the Principal Investigator or prepared by CQDM and approved by the Principal Investigator.

10.2 Any disclosure relating to the Project including publications, press releases or publicity shall mention the enabling structural support of CQDM and shall fairly represent the contribution of the other Parties as well as that of the Investigator(s) and the Granting Agency(ies) in accordance with rules established by the Granting Agency(ies) from time to time.

10.3 No Party shall use any other Party's name or trademark or any adaptation thereof without its prior written consent, except as stated in this section.

11. REPRESENTATIONS AND COVENANTS

11.1 Each of the Parties hereby respectively and independently represents to the other Party(ies) that:(i) it has full power, authority and capacity to enter into and perform its obligations pursuant to the Agreement and to consummate the transactions contemplated herein; (ii) it holds all rights, including intellectual property rights, allowing it to carry out the agreement and perform the Project; (iii) the execution, delivery and performance of the Agreement have been duly authorized by all necessary corporate action and constitute a legal, valid and binding obligation; (iv) there is no provision in its charter documents and, to the best of its knowledge, no provision in any existing obligation, contract or agreement to which it is bound that would be contravened by the execution, delivery or performance of the Agreement; (v) neither the performance, nor the compliance with the Agreement shall contravene any provision of the laws of any jurisdiction, including, without limitation, any statute, rule, regulation, judgement, decree, order, franchise or permit of any governmental body applicable to it; (vi) there is no action or proceeding pending or, to the best of its knowledge, threatened in writing against it before any court, administrative agency or other tribunal which might have a material adverse effect on its ability to perform its obligations hereunder; and (vii) no representation, statement or warranty contained in the Agreement or other disclosure document provided to the other Party(ies) in connection with the Agreement and the Project, contains any untrue statement of a material fact, or omits to state any material fact which is necessary in order to make the statements contained therein not misleading.

11.2 Each of the Research Entities further respectively and independently represents and covenants that:

11.2.1 (i) it is duly constituted under the laws of the province of Québec or the laws of Canada; (ii) it has at least one establishment operating in the province of Quebec; and (iii) it will promptly inform CQDM in writing of any changes in that respect;

11.2.2 it has secured Third-Party Funds (if any) and will provide written confirmation thereof upon request;

11.2.3 (i) it has not claimed, and will not claim, reimbursement of Eligible Expenses from more than one source except when these sources are co-funding the Project as indicated in the Budget; (ii) it has not used, and will not use, Funds as matching funds for other projects or use funds received for other projects as Matching Funds in connection with the Project; and (iii) it will promptly inform CQDM of the award of other funding granted or received from any source for the Project; and;

11.2.4 it maintains and will maintain during the Term and for three (3) years thereafter, at its sole cost and expense,customary general liability insurance subscribed by similar research entities to cover Project related activities or is self-insured by a government authority for an amount and with such other terms as is customary in the industry for similar activities and will ensure, when applicable, that its research team members, including the Investigator(s) maintain professional order membership and professional liability insurances relevant to their Project related activities.

11.3 Each of the Co-Funder(s) further respectively and independently represents that it has sufficient funds available to provide its portion of the Matching Funds and in-kind contribution (if any) committed to the Project as further detailed in the Funding Structure.

12. TERM

12.1 The Agreement shall commence on the Effective Date and shall remain in full force and effect until the completion of the Project (the " **Term**") unless earlier terminated pursuant to these General terms & conditions.

12.2 Upon earlier termination for any reason or expiration of the Term, the Research Entity(ies), the Investigator(s), and their research team members shall immediately cease any work on the Project under the Agreement and cease further expenses of the CQDM Funds and each Research Entity shall repay in its entirety the portion of the CQDM Funds that it received in consideration of the performance of the Project and that it did not spend according to the Budget. Notwithstanding the above, the Co-Funders and the Lead Research Entity can agree in writing to continue the performance of the Project without any further liability on CQDM.

12.3 The expiration or termination of the Agreement shall not release a Party from any obligation which by its nature shall survive expiration or termination (including for clarity confidentiality and reporting) or any liability which have matured prior to expiry or termination, except as otherwise provided herein.

13. TERMINATION

CQDM may terminate the Agreement in whole or as to the concerned Party, with immediate effect upon written notice to the other Party(ies), if:

13.1 a Milestone or Deliverable is not attained or disclosed, a Report is not provided, a Party or an Investigator does not comply with any representation, warranty or obligation under the Agreement or any part of the Matching Funds (if any) is not paid in accordance with the Agreement, and such non-compliance is not cured within thirty (30) days following a prior written notice to that effect;

13.2 a Party or an Investigator provided untrue, inaccurate or misleading statement of a material fact, omitted to state any material fact information or made a false representation in the Project Proposal, the Agreement or a Report;

13.3 an event having a material impact on the Project occurs, Granting Agency(ies) Policies and Guidelines are not respected or the Granting Agency(ies) terminate(s) the funding of the Project or otherwise require(s) that the Project be terminated for public interest reasons; or

13.4 a Party ceases its activities or avails itself of, or becomes subject to, any proceeding under the bankruptcy laws.

14. OTHER RIGHTS AND RECOURSES

14.1 Notwithstanding anything contained herein and in addition to its other rights and recourses, CQDM may, in case of a situation listed in section 13 or a non-compliance with the Agreement (i) withhold or postpone any disbursement of CQDM Funds; (ii) unilaterally modify disbursement schedule established in the Payment Schedule; (iii) require reimbursement of CQDM Funds not spent in accordance with the Agreement or set them off against future disbursement(s); and/or (iv) require additional reporting from the Research Entity(ies).

14.2 In case of termination due to sections 13.2, 13.3 or 13.4, CQDM may, at the request of the Granting Agency(ies), further require reimbursement in whole or in part of CQDM Funds disbursed and the concerned Research Entity shall proceed with such reimbursement within ten (10) days.

14.3 Reimbursement of CQDM Funds hereunder will bear interest at the applicable rate applicable determined in accordance with section 28 of the *Tax Administration Act* (RLRQ, Chapter A-6.002) and effective on the date of payment of the amount is subject to reimbursement. Interest may be calculated retroactively from that date or on any other date determined by the Granting Agency(ies).

15. INDEMNIFICATION

15.1 Each of the Research Entities is responsible for any Liabilities caused by such Research Entity or that of its employees, agents, representatives or subcontractors or resulting from a breach of its obligations under the Agreement or the law in the performance of the Agreement. Each Research Entity shall indemnify and hold CQDM and their employees, directors, officers, agents and the Granting Agency(ies) harmless from and against any and all such Liabilities upon request.

15.2 To the maximum extent permitted by applicable law, in no event will either Party be liable to the other Party for any indirect, special, incidental or exemplary damages whatsoever, including but not limited to, loss of revenue or profit, lost or damaged data, business interruption or any other pecuniary loss whether based in contract, or other causes of action, even if such Party has been advised of the possibility of such damages, except in relation to gross negligence or wilful breach of this Agreement.

SYNERGIQC GENERAL TERMS & CONDITIONS

16. EXCLUSION OF WARRANTY

Except as specifically set out in the Agreement, neither the Research Entity(ies) nor the Investigator(s) makes any representation or warranty regarding the results of the Project and disclaim any warranty, express, legal or implied of merchantability or fitness for a particular purpose.

17. GENERAL PROVISIONS

17.1 Entire Agreement; Amendments, Interpretation . This Agreement supersedes all agreements previously entered between the Parties, whether written or verbal, in respect of the subject matter thereof and shall be binding upon the Parties hereto and their respective heirs, executors, administrators, legal representatives, successors and permitted assigns. No amendment of the Agreement shall be binding unless in writing and signed by all the Parties. The provisions of the Agreement are severable and should any provision(s) be determined to be invalid, illegal or unenforceable, the concerned provision(s) shall be stricken or modified, within the original intent of the Parties, to make the provision(s) valid and enforceable. The remainder of the Agreement shall remain in full force and effect. If at any time during the Agreement and thereafter any Party requests further documents, instruments or assurances in order to carry out the provisions hereof, then the Party or the Investigator from which such documents, instruments and assurances are requested shall make its best efforts to promptly execute and deliver any such documents, instruments and assurances and do all things reasonably necessary to carry out the provisions hereof, all at the cost and expense of the Party requesting such documents, instruments and assurance.

17.2 Assignment. No right or obligation related to the Agreement shall be assigned by any Party without the prior written consent of the other Parties.

17.3 Independence. The Parties are independent entities engaged in independent business, and none of the Parties nor any of its agents or employees shall be regarded as an agent or employee of another Party. Nothing herein shall be construed as reserving to any Party the right to control another Party in the conduct of its employees or business, nor shall any Party have the authority to make any promise, guarantee, warranty, or representation which will create any obligation or Liability whatsoever, whether express or implied, on behalf of another Party. The Parties are not *joint venturers* or partners in any sense.

17.4 Notices. All notices, requests, demands and other communications required or permitted under this Agreement shall be in writing and shall be sent by e-mail (with confirmation of delivery) and addressed as follows:

If to CQDM:
E-mail: contracts@cqdm.org
Attention: the CQDM President

or to such other e-mail address designated in writing by a Party to the other Party. Notices delivered by e-mail (with confirmation of delivery) shall be deemed received on the date sent, provided that such transmittal occurs prior to 5:00 P.M. Eastern Standard Time, and if sent thereafter, any e-mail shall be deemed received on the next following [business] day.

Failing the ability to send an e-mail Notice pursuant to this Section due to the receipt of an automated non delivery message from an e-mail system (a “bouncing email”), then such Notice shall be either hand delivered or mailed by overnight courier postage prepaid and addressed as follows:

If to CQDM:
630 René-Lévesque Blvd. West, 20th floor, Montreal (Quebec) H3B 1S6
Attention of: the CQDM President

17.5 Governing Law; Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws in force in the Province of Québec and the federal laws of Canada applicable therein, without regard to the principles of conflict of law. The Parties hereby elect to submit any dispute arising out of or related to this Agreement to the exclusive jurisdiction of the courts of the Province of Québec.

17.6 No Waiver of Rights. In order to be effective, any waiver, by any Party, of any right under the Agreement, must be in writing signed by an authorized representative of the Party making the waiver. No such waiver or failure of any Party to enforce a right or strict performance under the Agreement shall be deemed to be a waiver or forbearance which would in any way prevent such Party from subsequently asserting or exercising any such rights, making a claim not specifically waived, or requiring strict performance of the Agreement. No such waiver or failure to enforce shall affect the validity of the Agreement or be a continuing waiver excusing compliance with any provision of the Agreement in the future.

17.7 Currency. Amounts referred to in the Agreement are in Canadian dollars.

17.8 Execution in Counterparts. This Agreement may be executed in counterparts (including in portable document format (“PDF”)), each of which, when so executed and delivered, shall be deemed to be an original, and all of which counterparts, taken together, shall constitute one and the same instrument.

17.9 Language. The Parties have accepted that the Agreement and any notice thereunder be drawn up in English. *Les parties ont accepté que ce contrat et tout avis en découlant soient rédigés en anglais.*

[The remainder of this page is intentionally left blank.]

SCHEDULE 4

RULES ESTABLISHED BY THE GOVERNMENT OF QUÉBEC CONCERNING ELIGIBLE EXPENSES INCLUDING RELATED TRAVEL

Dépenses admissibles à la SUBVENTION

Les dépenses énumérées dans cette annexe sont admissibles aux fins du calcul de la SUBVENTION en vertu de la présente convention. Ces dépenses admissibles sont composées des coûts liés directement aux projets de recherche, de valorisation, de transfert et d’innovation du BÉNÉFICIAIRE.

Coûts directs des projets

Les coûts directs des projets font référence aux dépenses directement imputables aux projets financés ou réalisés par le BÉNÉFICIAIRE. Ils englobent notamment la rémunération du personnel de recherche, les bourses à des étudiants et d'autres frais directement imputables aux projets.

Coûts indirects des projets

Les coûts indirects des projets font référence à des dépenses de fonctionnement additionnelles découlant des projets de recherche, mais ne pouvant pas être spécifiquement imputées à ceux-ci.

Ils comprennent les frais liés à l'exploitation et à l'entretien des infrastructures, à la gestion et à l'administration des projets, ainsi qu'au respect des différents règlements et normes en vigueur.

Dépenses de projets
Coûts directs des projets

Postes de dépenses liés directement aux projets financés:

- Salaires, traitements et avantages sociaux (voir spécificités)
- Bourses à des étudiants
- Matériel, produits consommables et fournitures
- Achat ou location d'équipements (voir spécificités)
- Frais de gestion
- Frais de gestion d'exploitation de propriété intellectuelle
- Honoraires professionnels
- Frais de déplacement et de séjour liés à la réalisation du projet, en conformité avec les normes gouvernementales en vigueur énoncées dans le Recueil des politiques de gestion du gouvernement du Québec
- Compensations monétaires pour participation aux projets
- Frais de diffusion des connaissances
- Frais d'animaleries et de plateformes
- Frais liés aux contrats de sous-traitance

Coûts indirects des projets *(pour les dépenses encourues par les établissements universitaires, les centres hospitaliers affiliés, les collèges et les CCTT)*

Dépenses de fonctionnement additionnelles nécessaires à la réalisation des projets. Un taux fixe de **27%** est appliqué aux cinq postes de dépenses suivants des coûts directs des projets:

1) Salaires, traitements et avantages sociaux; 2) Bourses à des étudiants;
3) Matériel, produits consommables et fournitures; 4) Achat ou location d'équipements;
5) Frais de déplacement et de séjour.

Ces coûts directs, pour les cinq postes de dépenses, doivent avoir été financés par le Ministère

Spécificités:

- Les sommes liées à la libération des professeurs universitaires pour réaliser des activités dans le cadre des projets ne peuvent figurer dans ce poste de dépenses, à moins que l'établissement confirme par lettre le coût réel de la période de dégagement du chercheur de ses responsabilités habituelles.

- Les salaires, incluant les avantages sociaux des professeurs nouvellement recrutés par une institution académique sur la base d'une expertise reconnue, peuvent être couverts pour une période maximale de trois ans, tant qu'ils font partie d'une chaire de recherche qui se consacre à répondre aux besoins d'une industrie émergente au Québec.

- Les dépenses liées à l'achat de petits équipements ou à la location d'équipements sont d'un maximum de 25% du total des dépenses admissibles. La valeur d'achat de chaque équipement doit être égale ou inférieure à 25 000 $ avant les taxes.

Dépenses admissibles et barème des frais de déplacement

Les frais de déplacement réfèrent aux frais encourus alors qu'une personne se déplace à l'extérieur de son territoire habituel de travail.

La présente annexe présente un résumé du recueil des politiques de gestion en vigueur au gouvernement du Québec concernant les directives relativement aux frais de déplacement qui doivent être suivies par le BÉNÉFICIAIRE et qui sont indiquées sur le site Web se trouvant au lien suivant: https://www.tresor.gouv.qc.ca/fileadmin/PDF/secretariat/Directive_frais_remboursables.pdf

a) Frais de déplacement au Québec

Les frais de déplacement réfèrent aux frais encourus alors qu'une personne se déplace à l'extérieur de son territoire habituel de travail.

La présente annexe concerne les frais de déplacement liés à certains modes de transport, à l'hébergement en établissement hôtelier, ainsi qu'aux frais de restaurant.

Transport

Le recours au transport en commun doit être favorisé dans la mesure où cela est plus économique que l'usage d'un véhicule personnel.

Lors de l'utilisation d'un véhicule personnel, les taux suivants sont admissibles selon le kilométrage applicable au cours de l'exercice financier du BÉNÉFICIAIRE:

Kilométrage annuel	Taux
1re tranche : 1 – 8 000 km	0,590 $/km
2e tranche : plus de 8 000 km	0,530 $/km

Si un moyen approprié de transport en commun est disponible et qu'un véhicule personnel est utilisé, le taux admissible est réduit à 0,170 $ par kilomètre ainsi parcouru.

Hébergement en établissement hôtelier

Les indemnités quotidiennes maximales sont les suivantes pour l'hébergement dans un établissement hôtelier:

	Indemnités maximales	
Ville	Basse saison (Du 1er novembre au 31 mai)	Haute saison (Du 1er juin au 31 octobre)
Territoire de la ville de Montréal	151 $	166 $
Territoire de la ville de Québec	127 $	
Villes de Laval, Gatineau, Longueuil, Lac- Beauport et Lac-Delage	122 $	132 $
Établissements situés ailleurs au Québec	100 $	104 $
Tout autre établissement	95 $	

Frais de repas

Les indemnités quotidiennes maximales sont les suivantes:

	Taux applicables
Déjeuner	13,75 $
Dîner	18,90 $
Souper	28,50 $
Total	**61,15 $**

Les taux ci-dessus incluent les taxes et les pourboires.

b) Frais de déplacement hors du Québec

La présente section concerne les frais encourus hors du Québec pour les programmes dans lesquels ce type de frais s'applique.

Un barème tenant compte des variations de taux de change est édité par le Conseil du trésor et disponible sur demande auprès du ministère de l'Économie et de l'Innovation (MEI).

Transport

Le recours au transport en commun doit être favorisé dans la mesure où cela est plus économique que l'usage d'un véhicule personnel.

La copie du billet de train, d'avion ou de location de véhicule est exigée à titre de pièce justificative, ainsi que la copie de la facture d'achat.

Pour les billets de transport urbain, le justificatif d'achat est exigé pour la demande de remboursement de plus d'un trajet (exemple : billet forfaitaire à la journée/sur plusieurs jours ou billet par 10 unités).

En cas d'utilisation d'un véhicule personnel pour un déplacement au Canada ou aux États-Unis, un calcul basé sur le coût moyen du litre d'essence au Québec et aux États-Unis s'applique. Les résultats du calcul des indemnités de kilométrage allouées lors de déplacements à l'extérieur du Canada seront fournis sur demande.

Hébergement et repas en établissement hôtelier

Le barème appliqué est celui utilisé par les délégations du Québec à l'étranger; il peut être obtenu auprès du MEI.

Les montants maximaux portés au barème n'incluent pas les taxes en vigueur dans les pays concernés qui, lorsqu'elles sont appliquées, doivent être remboursées en sus.

À titre de pièce justificative, la facture et la preuve de paiement sont exigées.

Taux de change

Tout écart de tarification découlant des variations des taux de change entre les frais de repas et d'hébergement encourus et la tarification prévue par le Conseil du trésor peut être remboursable sur présentation de pièces justificatives témoignant du taux de conversion de la monnaie canadienne en monnaie locale.

SCHEDULE 5

IP MANAGEMENT AND COMMERCIALIZATION AGREEMENT

[See attached document]

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

a departmental corporation forming part of the Government of Canada created by the *National Research Council Act* (R.S.C. 1985, c. N-15), and an agent of His Majesty the King in Right of Canada

whose head office address is: 1200 Montreal Road, Ottawa, Ontario K1A 0R6 Canada for its 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 **"Oragenics" or "Collaborator-1**")

a corporation under the laws of the State of Florida, United States of America

whose address is: 4902 Eisenhower Boulevard - Suite 125- Tampa, Florida 33634, U.S.A.

Business Contact: Kim Murphy - Email: kmurphy@oragenics.com
Technical contact: Terrence Cochrane - Email: t.c@brevisrefero.com

AND: **INSPIREVAX INC.** (called **"InspireVax" or "Collaborator-2")**

a corporation under the laws of the Province of Quebec, Canada

whose address is: 46 rue de Saint-Tropez,
Kirkland, Quebec H9J 2K6 Canada

Contact: Joseph Zimmermann - E-mail: joseph@inspirevax.com

(Individually referred to as a "Party" and collectively referred to as the "Parties"; Collaborator-1 and Collaborator-2 individually referred to as "Collaborator" and collectively referred to as "Collaborators")

WHEREAS

a) The Parties have submitted a grant application with NRC reference number A-0045024 (hereinafter called the **"Grant Application")** to the Consortium Quebecois pour le Developpement des Medicaments (hereinafter referred to as **"CQDM")** to obtain funding from the Government of Quebec for the performance of the Project described in the Statement of Work of this Agreement.

b) The Parties to this Agreement and the CQDM have signed a funding agreement with NRC reference number A-00xyz (hereinafter the **"Funding Agreement")** for the purpose of funding the Project as defined herein below.

c) As per the Funding Agreement, the CQDM committed to fund up to 40% of the eligible costs of the Project (hereinafter referred to as the **"CQDM Funds")** and the Collaborators committed to fund the remaining portion of the Project funding not covered by the CQDM Funds.

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

1. This Agreement concerns scientific research and development, called the "Project", described as " ***Development of a Variant-Agnostic COVID-19 Protein Antigen Candidate for a Multivariant Intranasal Vaccine".***

National Research Council Canada | Conseil national de recherches Canada | **Collaborative Research Agreement**
Non-Exclusive Licence Included ☐

Business Confidential-Protected B

12. 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 **Collaborator-1** at Tampa, Florida, U.S.A.

ORAGENICS INC.

Date: May 16, 2023

Per: */s/ Kimberly Murphy*
Kimberly Murphy

SIGNED by the **Collaborator-2** at Kirkland, Quebec, Canada

INSPIREVAX INC

Date: May 23, 2023

Per: */s/ Joseph Zimmerman*
Joseph Zimmerman - CEO

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

NATIONAL RESEARCH COUNCIL OF CANADA

Date: May 9, 2023

Per: */s/ Lakshmi Krishnan*
Lakshmi Krishnan -Vice President
Life Sciences Division

ANNEX IP: INTELLECTUAL PROPERTY

IP-1 **NATURE OF THE PROJECT:** By the nature of the Project, Arising Intellectual Property that may arise is difficult to predict, and the Parties consider it desirable to defer settling the terms on which it will be available until the Arising Intellectual Property is known.

IP-2 **DEFINITIONS:**

2.1 **"Arising Intellectual Property"** or **"Arising IP"** is Intellectual Property that is developed in the Project and that is disclosed in the Deliverables. The possessive adjective "the NRC's" or "other Party's" or "Collaborator-1's" or "Collaborator-2's" indicates ownership or control by that Party. For clarity, any improvement solely to BDX301 that excludes antigen shall not constitute Arising IP under this Agreement, and any improvement solely to BDX301 that excludes antigen shall be assigned to Inspirevax.

2.2 **"Background IP"**is IP that is developed or conceived by a Party prior to the Effective Date of this Agreement. The possessive adjective "the NRC's" or "other Party's" or "Collaborator- 1's" or "Collaborator-2's" indicates ownership or control by that Party.

2.3 **"BDX301"** means an adjuvant owned or controlled by Collaborator-2 to be used in this Project for the purposes of testing the antigens.

2.4 **"Commercially Exploit"** is to use, reproduce and modify Arising IP, and to manufacture, use, import, and sell articles embodying or made by use of any Deliverables and to provide services by the use of any Deliverables.

2.5 **"Confidential Non-Project Information"** means any confidential or proprietary information, either of a business or technical nature, other than Arising Intellectual Property, disclosed by one Party to the other Party or Parties pursuant to this Agreement.

2.6 **"Deliverables"** are the tangible results of the Project, such as reports, physical models, samples, and data records that are specifically mentioned in the Statement of Work and Deliverables as being deliverable.

2.7 **"Intellectual Property"** or **"IP"** is all rights in inventions {whether patentable or not), patents, copyright material, trade secrets, confidential information and bacterial, viral, plant, human, or animal material that has new genetic or other characteristics first produced by a Party.

IP-3 **ARISING INTELLECTUAL PROPERTY:** The Parties represent that, by law or contract, they will own any Arising IP created by their employees. A Party who is the sole owner of Arising IP is responsible for patenting and licensing its Arising IP, but is not obliged by this Agreement to patent its Arising IP. However, a Party who is unwilling to patent its Arising IP shall diligently do so if the other Party undertakes to pay all reasonable expenses incurred in obtaining and maintaining the patent.

IP-4 **JOINTLY CREATED ARISING IP:** In the case of Arising IP that was created by employees of two or more Parties, the other Parties hereby assigns their entire rights in that Arising IP to the NRC and agrees to execute and deliver any further documents and to give any further assurances that the NRC may request. It will then be regarded as the NRC's Arising IP and that Arising IP shall be treated as the NRC's Arising IP for all purposes under this Agreement.

IP-5 **SHARING INFORMATION:** The Parties shall keep each other promptly informed of Arising IP. Each Party shall give the other, for information only, a copy of any patent application for Arising IP immediately upon filing the application, and a copy of related correspondence with a patent office if requested, and the information contained in such documents and correspondence will be maintained in confidence.

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Non-Exclusive Licence Included ☐

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IP-6 **LICENCE OF THE NRC'S ARISING IP:** The NRC and Collaborator-1 entered into a license agreement for certain NRC technologies signed by the NRC and Collaborator-1 on July 26th 2021 with NRC reference number A-0039781 (hereinafter referred to as the **"NRC-Collaborator-1 License").** In case of creation of NRC's Arising IP, the NRC undertakes to negotiate with the Collaborator-1 in good faith to settle the terms of an amendment to the NRC-Collaborator-1 License or a separate exclusive license agreement limited to intranasal vaccine applications which will allow Collaborator-1 to Commercially Exploit the NRC's Arising IP, upon request by Collaborator-1 no later than six (6) months after the end of the Project and subject to obtaining the then required NRC's management approvals.

IP-7 **LICENCE OF OTHER PARTY'S ARISING IP:** The other Parties hereby grant to the NRC a fully prepaid and royalty-free licence for all the other Party's Arising IP and Background IP solely for research purposes within the NRC, for performing the Project. In addition, the other Party, at the NRC's request, shall negotiate with the NRC in good faith to settle the terms of a licence which will allow the NRC to exploit the other Party's Arising IP for research purposes and subject to obtaining the then required management approvals from the relevant Party(ies).

IP-8 **NON-PROJECT TECHNOLOGY:** If, in order to perform work in the course of the Project, a Party needs another Party's IP that is not part of the Arising IP, a non-exclusive licence for that limited purpose is granted by this Agreement and terminates at the end of the Project. Any other licence must be negotiated.

IP-9 **CONFIDENTIAL NON-PROJECT INFORMATION RESTRICTIONS:** Unless otherwise stipulated in a separate agreement, the following provisions apply to Confidential Non-Project Information that is in electronic, written, graphic or other tangible form, including a physical object, that is clearly marked "Proprietary" or "Confidential" or with an equivalent legend, or that is oral information provided that at the time of disclosure the disclosing Party clearly identifies the confidential nature of such information and confirms such confidential nature by transmitting the information, in a written version that is marked as above, to the receiving Party within 20 days of disclosure. The receiving Party agrees not to disclose any Confidential Non-Project Information, including to any director, officer or employee of the receiving Party unless that individual needs the information to perform work in the course of the Project and is legally bound to keep confidences. In protecting Confidential Non-Project Information, the receiving Party must use at least the same degree of care as it uses to protect its own information of a similar nature, but not less than a reasonable degree of care. Unless specifically licensed, Confidential Non-Project Information may only be used by the receiving Party to perform work in the course of the Project. These obligations of confidentiality and protection will initially apply to Confidential Non-Project Information in the form of oral information but will cease to apply if the information is not provided in a written version within 20 days of disclosure. Notwithstanding the foregoing, the receiving Party 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 such information.

IP-10 **END OF CONFIDENTIAL NON-PROJECT INFORMATION RESTRICTIONS:** Unless otherwise stipulated in a separate agreement, all obligations of confidentiality and restrictions on the use of Confidential Non-Project Information in this Agreement cease to apply five (5) years after the expiration of this Agreement and such obligations and restrictions do not apply to information that can be proved to be:

10.1 independently developed by the receiving Party without reference to or use of the confidential information of the other Party;

Exhibit 31.1

CERTIFICATION

I, Kimberly Murphy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date : August 11, 2023

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

Exhibit 31.2

CERTIFICATION

I, Janet Huffman, certify that:

b. 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-15I and 15d-15I) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(b) 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;

I 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:

(b) 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.

Date: August 11, 2023

By: */s/ Janet Huffman*
Janet Huffman
Principal Financial Officer

Exhibit 32.1

Certification of Principal Executive Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Kimberly Murphy, hereby certify, to the best of my knowledge, that:

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

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

/s/ Kimberly Murphy
Name: Kimberly Murphy
President and Principal Executive Officer

Date: August 11, 2023

Exhibit 32.2

Certification of Principal Financial Officer

Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350)

In connection with the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Janet Huffman, 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/ Janet Huffman
Name: Janet Huffman
Principal Financial Officer

Date: August 11, 2023