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 March 31, 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 May 9, 2023, there were 2,024,657 shares of Common Stock, $.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-month period ended March 31, 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-month period ending March 31, 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-month period ended March 31, 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-month period ended March 31, 2022 in this Form 10-Q for the three-month period ended March 31, 2023 the financial information reflects the restated financials as reported in Amendment 1.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.
Consolidated Balance Sheets

	March 31, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 9,158,340	$ 11,426,785
Prepaid expenses and other current assets	2,544,713	2,844,798
Total current assets	11,703,053	14,271,583
Property and equipment, net	109,759	121,062
Deposit	17,940	17,940
Operating lease right-of-use assets	298,724	347,440
Total assets	$ 12,129,476	$ 14,758,025
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,470,505	$ 1,124,197
Short-term notes payable	107,890	267,640
Operating lease liabilities	202,187	204,447
Total current liabilities	1,780,582	1,596,284
Long-term liabilities		
Operating lease liabilities	104,463	152,439
Total long-term liabilities	104,463	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 March 31, 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 March 31, 2023 and December 31, 2022	2,025	2,025
Additional paid-in capital	197,057,037	196,977,071
Accumulated deficit	(188,407,354)	(185,562,517)
Total shareholders' equity	10,244,431	13,009,302
Total liabilities and shareholders' equity	$ 12,129,476	$ 14,758,025

See accompanying Report of Independent Registered Public Accounting Firm and notes to the consolidated financial statements.

Oragenics, Inc.
Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended March 31,	
	2023	**2022 As Restated**
Grant revenue	$ 17,024	$ 15,083
Operating expenses:		
Research and development	1,672,576	3,293,661
General and administrative	1,249,263	1,331,549
Total operating expenses	2,921,839	4,625,210
Loss from operations	(2,904,815)	(4,610,127)
Other income (expense):		
Interest income	62,201	11,906
Interest expense	(3,347)	(3,246)
Local business tax	—	(490)
Miscellaneous income	1,124	10,964
Total other income, net	59,978	19,134
Loss before income taxes	(2,844,837)	(4,590,993)
Income tax benefit	—	—
Net loss	$ (2,844,837)	$ (4,590,993)
Basic and diluted net loss per share	$ (1.41)	$ (2.29)
Shares used to compute basic and diluted net loss per share	2,024,766	2,002,946

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

	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 As Restated	2,002,946	$ 2,003	16,017,000	$ 2,656,713	$ 195,191,858	$ (175,865,121)	$ 21,985,453

See accompanying notes.

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

	For the Three Months Ended March 31,	
	2023	**2022 As Restated**
Cash flows from operating activities:		
Net loss	$ (2,844,837)	$ (4,590,993)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11,303	8,468
Gain on sale of property and equipment	—	(10,964)
Stock-based compensation expense	79,966	90,247
Changes in operating assets and liabilities:		
Other receivables	—	6,987
Prepaid expenses and other current assets	300,085	(1,287,175)
Operating Lease Right of Use Assets	48,716	45,921
Accounts payable and accrued expenses	346,309	147,884
Change in Operating Lease Liabilities	(50,237)	(47,327)
Net cash used in operating activities	(2,108,695)	(5,636,952)
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	(159,750)	(181,241)
Net cash provided by (used in) financing activities	(159,750)	(181,241)
Net increase (decrease) in cash and cash equivalents	(2,268,445)	(5,893,240)
Cash and cash equivalents at beginning of period	11,426,785	27,265,703
Cash and cash equivalents at end of period	$ 9,158,340	$ 21,372,463
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,347	$ 3,246

See accompanying notes.

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

1. Organization

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

2. Basis of Presentation

The accompanying unaudited interim consolidated financial statements as of March 31, 2023 and December 31, 2022 (audited) and three months ended March 31, 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 March 31, 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-month period ended March 31, 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-month period ending March 31, 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-month period ended March 31, 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-month period ended March 31, 2022 in this Form 10-Q for the three-month period ended March 31, 2023 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 $2,844,837 and used cash of $2,108,695 in its operating activities during the three months ended March 31, 2023. As of March 31, 2023, the Company had an accumulated deficit of $188,407,354.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes the working capital at March 31, 2023 will be sufficient to meet the business objectives as presently structured through the fourth quarter of 2023. As such, there is substantial doubt that we can continue as a going concern beyond that date.

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

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

3. Significant Accounting Policies

Basis of Consolidation

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

New Accounting Standards

There are no additional accounting pronouncements issued or effective during the three months ended March 31, 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 Statement of Cash Flows for the three-month period ended March 31, 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
- Changes in Operating Lease Liabilities of ($47,327) was reclassified from Accounts Payable and Accrued Expenses

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

Stock-Based Compensation

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

Warrants

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

Net Loss Per Share

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

Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes it is not exposed to any significant credit risk on cash and cash equivalents. As of March 31, 2023, the uninsured portion of this balance was $8,908,340. As of December 31, 2022, the uninsured portion of this balance was $11,176,785.

Grant Revenue

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

4. Property and Equipment, net

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

	March 31, 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	(1,374,542)	(1,363,239)
Property and equipment, net	$ 109,759	$ 121,062

Depreciation and amortization expense for the three months ended March 31, 2023 and March 31, 2022 was $11,303 and $8,468 respectively.

5. Accounts Payable and Accrued Expenses

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

	March 31, 2023	December 31, 2022
Accounts payable trade	$ 939,013	$ 246,690
Accrued Expense	488,372	812,861
Professional fees	-	31,101
Vacation	43,120	33,545
Total accounts payable and accrued expenses	$ 1,470,505	$ 1,124,197

6. Short-Term Notes Payable

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

	March 31, 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, 2023 and May 24, 2022, respectively	$ 107,890	$ 267,640

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 March 31, 2023 and December 31, 2022:

	March 31, 2023	December 31, 2022
Prepaid Research and Development Expense	2,256,983	2,471,809
Prepaid Insurance	212,730	372,989
Prepaid Financing costs	75,000	-
Total	2,544,713	2,844,798

As of March 31, 2023 and December 31, 2022, the Company had $2,544,713 and $2,844,798 in prepaid expenses, respectively. The balance at March 31, 2023 reflects approximately $2.3 million of prepaid expense to third-party vendors for research and development to be completed, $0.08 million of prepaid financing costs related to the Company's At-The-Market Program and approximately $0.2 million in prepaid insurance.

8. Shareholders' Equity

Common Stock

Approval of a 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-month period ended March 31, 2022, have been adjusted to reflect the effect of the reverse split.

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

For the three-month periods ended March 31, 2022 and 2023 the Company did not issue any shares of common stock under its ATM program.

During the six- and nine- month periods ending June 30, 2022 and September 30, 2022 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 Company intends to use the net proceeds of the offering primarily 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 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 three months ended March 31, 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-month periods ended March 31, 2022 and 2023 the Company issued no additional shares of common stock.

During the three-month period ended September 30, 2022 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 commons 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 shall rank (i) on par with the Common Stock and Series A Preferred Stock and junior to Series C Preferred Stock as to dividend rights and (ii) junior to Series C Preferred Stock, on par with Series A Preferred Stock and senior to the Common Stock as to distribution of assets upon liquidation, dissolution or winding-up by us, whether voluntary or involuntary.

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

9. Warrants

The Company's outstanding and exercisable warrants as of March 31, 2023 are presented below:

Exercise Price	Total Warrants Outstanding	Exercisable Warrants Outstanding	Expiration Date
$ 120.00	15,000	15,000	4/10/2023
$ 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
	275,995	275,995	

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. 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 March 31, 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 $79,966 and $90,247 for the three months ended March 31, 2023 and 2022, respectively. As of March 31, 2023, there was approximately $182,475 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 three-months ended March 31, 2023, the Company granted 7,000 stock options to the Chief Financial Officer as an onboarding award. The fair value of this award was $3.92 per share of common stock. 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 three-month period ended March 31, 2023:

	Three-months ended March 31, 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 to include the Delta and Omicron variants. In addition, the Company subsequently amended the License Agreement to broaden the non-exclusive field of use to include all diseases caused by coronaviruses and any genetic variants thereof. Additional amendments to the License Agreement removed certain protocols and reagents from the License Agreement, and 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.

During the three months ended March 31, 2021, 41,210 warrants were 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 three-month period ended March 31, 2023, there are 32,033 warrants outstanding carrying an exercise price of $54.00 that expire on March 25, 2024.

Inspirevax License

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 consolidated financial statements as they are incurred.

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.

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 three-months ended March 31, 2023 was approximately $41,426. 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. In November of 2019, the Company entered into an amendment for the Tampa facility for a term of three years beginning in March of 2020. In August of 2022, the Company entered into an amendment for the leased office space for twelve months commencing on March 1, 2023. Lease payments are $4,944 per month inclusive of insurance, taxes and utilities. The lease expires on February 29, 2024. Total rent expense under this lease was approximately $16,700 for the three-months ended March 31, 2023.

	For the Three Months Ended March 31, 2023	For the Twelve Months Ended December 31, 2022
Weighted Average Remaining Lease Term In Years		
Operating leases	1.46	1.72
Weighted Average Discount Rate		
Operating leases	5.70%	5.78%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2023	164,535
2024	156,605
2025	-
Total	$ 321,140
Less: effect of discounting	(14,491)
Present value of lease liabilities	$ 306,649

The cost component of operating leases is as follows:

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Operating lease cost	$ 57,755	$ 57,129
Short-term lease cost	-	1,634
Total lease cost	$ 57,755	$ 58,763

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

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ (59,274)	$ (58,535)

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). In late April of 2023, the World Health Organization's estimates indicate the number of worldwide COVID-19 infections have exceeded 763 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. The Janssen vaccine is currently available in the United States under Emergency Use Authorizations ("EUA") by the FDA. In July 2022, the FDA granted EUA for the Novavax COVID-19 vaccine as well. 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.

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.

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 $1,672,576 and $3,293,661 for the three months ended March 31, 2023 and March 31, 2022, respectively. Our research and development costs are tracked by our COVID vaccine program and our lantibiotics program.

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.

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 local business taxes, gain on sale of property and equipment, as well as interest income and expense. Interest income consists of interest earned on our cash and cash equivalents, and interest earned on the stock subscription receivable. The primary objective of our investment policy is capital preservation. Interest expense consists primarily of interest and costs associated with our indebtedness.

Income Taxes

At December 31, 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 March 31, 2023 and 2022

Grant revenue. Grant revenue was $17,024 for the three months ended March 31, 2023 compared to $15,083 for the three months ended March 31, 2022, an increase of $1,941, or 13%. This increase was attributable to awards received for a small business innovation research grant.

Research and Development. Research and development expenses were $1,672,576 for the three months ended March 31, 2023 compared to $3,293,661 for the three months ended March 31, 2022, a decrease of $1.6 million or 49%.

	For the Three Months Ended March 31, 2023	For the Three Months Ended March 31, 2022
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	277,286	391,088
COVID Vaccine Development Expense		
Clinical Research	442,549	414,949
Non-clinical research and development activities	952,741	2,487,624
Total Research and development activities	**$ 1,672,576**	**$ 3,293,661**

This decrease was primarily due to approximately $1.5 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, patent costs, and other administrative overhead expenses of approximately; $63,00, $35,000, and $50,000 respectively. These decreases were partially offset by increases in supplies, repairs, rent and utilities, and depreciation expense of approximately; $7,000, $5,000, $34,000, and $2,000 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 $1,249,263 for the three months ended March 31, 2023 compared to $1,331,549 for three months ended March 31, 2022, a decrease of $0.08 million or 6% 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 $0.1 million, and
- Other overhead related expenses for salaries and wages, travel, insurance, and supplies of approximately $0.08 million

These expense decreases were offset by increases in:

- Consultant expense for third party accounting support as a new Chief Financial Officer was identified of approximately $0.1 million,
- Legal expenses related to our ATM and Reverse Stock Split in the three-month period ended March 31, 2023 of approximately $0.2 million, and
- Increased rent expense of approximately $0.05 million

Other Income. Other income, net was $59,978 for the three months ended March 31, 2023 compared to $19,134 for the three months ended March 31, 2022, resulting in an increase of $40,844. The net change was primarily attributable to an increase in interest income of $50,295, for the three-month period ended March 31, 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 three months ended March 31, 2023 and March 31, 2022 our operating activities used cash of $2,108,695, and $5,636,952, 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 $9,922,471 and $12,675,299 at March 31, 2023 and December 31, 2022, respectively.

During the three months ended March 31, 2023 and March 31, 2022, our investing activities used cash of $-0- and $(75,047) respectively.

During the three months ended March 31, 2023 and March 31, 2022, our financing activities used cash of $(159,750) and $(181,241) respectively. The cash used by financing activities during the three months ended March 31, 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. Any Shares offered and sold in the ATM Program were issued pursuant to our universal shelf registration statement on Form S-3 (the "Shelf Registration Statement") of which $9,671,869 remained available under our Shelf Registration Statement at September 30, 2022. The ATM Program will terminate upon (a) the election of the Agent upon the occurrence of certain adverse events, (b) 10 days' advance notice from one party to the other, or (c) the sale of the balance available under our Shelf Registration Statement. Under the terms of the Sales Agreement, the Sales Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Sales Agreement.

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.

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 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 three-month period ended March 31, 2023 the Company did not issue any shares of common stock under its 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.

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 September 30, 2022 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 (ii) shares of Common Stock to the Series B holders in connection with the Preferred Stock Financing. As of March 31, 2023, there are 11,828 and 11,720 shares of common stock 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. 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 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 three months ended March 31, 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 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, 2021 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed on March 24, 2022. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption "Risk Factors" in our Annual Report on Form 10-K.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately and $2.8 million and $4.6 million for the three months ended March 31, 2023 and March 31, 2022, respectively, and approximately $14.3 million and $15.7 million for the years ended December 31, 2022, and 2021, respectively. As of March 31, 2023, our accumulated deficit was approximately $188.4 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 could increase 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. 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.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference			Filing date	Filed herewith
		Form	File no.	Exhibit		
3.1	Amended and Restated Articles of Incorporation as amended prior to December 29, 2017 (including certificates of designation of Series A, B and C Preferred Stock)	8-K	001-32188	3.1	12/29/17	
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017	8-K	001-32188	3.2	12/29/17	
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018	8-K	001-32188	3.1	1/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.4	6/26/18	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.5	2/28//22	
3.6	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.7	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.8	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.9	Third Amendment to Bylaws	8-K	001-32188	3.9	2/28/22	
10.1	National Research Council (NRC) Canada Technology License Agreement (dated July 26, 2021) and Amendment One (dated September 2, 2021).*	10-Q	001-32188	10.0	11/15/21	
10.2	NRC Technology License Amendment 2	10-K	001-32188	10.6	3/24/22	
10.3	NRC Technology License Amendment 3	10-K	001-32188	10.7	3/24/22	
10.4	NRC Technology License Amendment 4	10-Q		10.4	8/9/22	
10.5	Inspirevax License Agreement*					X
10.6	Executive Employment Agreement for Ms. Huffman dated effective March 7, 2023	8-K		10.1	3/8/23	
10.7	NRC Technology License Amendment 5*					X
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.					X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).					X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).					X
101.INS	Inline XBRL Instance Document					
101.SCH	Inline XBRL Taxonomy Extension Schema					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase					X

104	Cover Page Interactive Data File (embedded within the Inline XBRL document

* 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 12th day of May 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 10.5

[***] 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.

COMMERCIAL LICENSE AGREEMENT

THIS COMMERCIAL LICENSE AGREEMENT (the "**Agreement**") is made and entered into effective as of February 21, 2023 (the "**Effective Date**") by and between **INSPIREVAX INC.**, a corporation incorporated in accordance with the federal laws of Canada, with a registered office at 46 rue de Saint-Tropez, Kirkland, Québec, Canada, H9J 2K6 ("**Inspirevax**"), and **ORAGENICS, INC.,** a Florida corporation having its principal place of business at 4902 Eisenhower Blvd., Suite 125, Tampa, FL 33634 ("**Oragenics**"). Inspirevax and Oragenics may be referred to herein individually as a "**Party**", and collectively as the "**Parties**."

RECITALS

WHEREAS, Inspirevax owns, licenses, or controls all of the rights, title and interests in and to certain patents and know-how relating to the BDX Product (as defined below), and Inspirevax desires to further research, develop, manufacture, and distribute a Combination Product including the BDX Product therein;

WHEREAS, Inspirevax is willing to grant global exclusive rights to Oragenics in respect of the patents and know-how related to the BDX Product for Oragenics in the Field to conduct non-clinical and clinical research and development trials, manufacture, and distribute the Combination Product in the Territory;

NOW THEREFORE, in consideration of the foregoing and the covenants and promises contained herein, and intending to be legally bound, the Parties agree as follows:

ARTICLE 1
DEFINITIONS

As used in this Agreement, the following capitalized terms shall have the following meanings:

1.1 "**Affiliate**" means, with respect to a particular Party, any other person or entity that directly or indirectly controls, is controlled by, or is in common control with such Party. As used in this Section 1.1, the term "controls" (with correlative meanings for the terms "controlled by" and "under common control with") means the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of an entity, or the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of voting securities, by contract, or otherwise.

1.2 "**Antigen**" means a coronavirus protein or other antigenic component or related molecule or molecules which when administered to a mammal, with or without a coadministered adjuvant, gives rise to an immune response against a coronavirus.

1.3 "**Applicable Laws**" has the meaning set forth in Section 8.2(d)(xi).

1.4 "**Authorizations**" has the meaning set forth in Section 8.2(d)(xi).

1.5 "**BDX Product**" means BDX300 or BDX301, a novel lipid-protein based adjuvant, as further described in **Schedule C**.

1.6 "**Claims**" has the meaning set forth in Section 9.1.

1.7 "**Combination Product**" means an intra-nasal vaccine composed of the BDX Product and the Antigen.

1.8 "**Commercialization**" means any and all activities, other than Development and manufacturing activities, directed or relating to the offering for sale or sale of a product, including activities relating to marketing, promoting, distributing, selling and offering to sell such product. For clarity, Commercialization activities shall also include planning and implementation, booking of sales, pricing and reimbursement activities, subject as applicable to the terms and conditions of this Agreement.

1.9 "**Confidential Information**" means each Party's Information disclosed pursuant to this Agreement or any other confidentiality agreement between the Parties and shall include, without limitation, manufacturing, technical, marketing, financial, personnel and other business information and plans, whether in oral, written, graphic or electronic form.

1.10 "**Control**" means, with respect to Information, a Patent or any other form of intellectual property, that a Party owns or has a license from a Third Party and has the ability to grant a license or sublicense as required under this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

1.11 "**Delivery Improvements**" means any improvements, development and intellectual property, whether developed or reduced to practice pursuant to the terms of the Research Agreement or this Agreement, including the study and clinical data (including the Study Data) related to the nasal delivery of the BDX Product alone or in combination with another moiety. For the avoidance of doubt, rights solely related Delivery Improvements do not include any rights and/or assets related to the Combination Product and/or Antigen.

1.12 "**Development**" means all activities, or requested or required by a Regulatory Authority as a condition or in support of, seeking, obtaining, maintaining or expanding any Regulatory Approval (including the Marketing Authorization) in country of the Territory, including activities related to research, preclinical and other non-clinical testing, quality assurance/quality control, clinical studies, statistical analysis and report writing, the preparation and submission of Regulatory Approval applications. When used as a verb, "Develop" means to engage in Development.

1.13 "**FDA**" has the meaning set forth in Section 8.2(d)(xi).

1.14 "**Field**" means the use of intra-nasal vaccines in humans for the prevention or treatment of diseases caused by coronaviruses and any genetic variants thereof.

1.15 "**Governmental Authority**" means any supra-national, federal, national, state, regional, local, municipal, provincial or other Governmental Authority of any nature (including any governmental division, prefecture, subdivision, department, agency, bureau, branch, office, commission, council, court, arbitral body or other tribunal).

1.16 "**Gross Revenues**" shall mean gross revenues, as defined in accordance with IFRS.

1.17 "**GSK License**" means the license agreement entered into Inspirevax, previously known as Biodextris Inc., and ID Biomedical Corporation dated October 12, 2017, as amended from time to time.

1.18 "**IFRS**" means the International Financial Reporting Standards, as issued by the International Accounting Standards Board.

1.19 "**Information**" means information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, including without limitation, databases, inventions, practices, methods, techniques, technical information and data, specifications, formulations, formulae, knowledge, know-how, skill, experience, information related to manufacturing, marketing, financials, personnel, the Party's respective businesses and business plans, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.

1.20 "**Inspirevax Improvements**" has the meaning set forth in Section 6.1(a).

1.21 "**Inspirevax Indemnitees**" has the meaning set forth in Section 9.2.

1.22 "**JDC**" has the meaning set forth in Section 2.1.

1.23 "**Inspirevax Know-How**" means all Information related to the BDX Products (other than Inspirevax Patents) that (a) is Controlled by Inspirevax as of the Effective Date, and (b) is reasonably required or useful for Oragenics to conduct the applicable clinical and non-clinical research and trials, manufacture and distribution of the Combination Product.

1.24 "**Inspirevax Patents**" means all Patents set forth in **Schedule B** hereto as related to the BDX Products.

1.25 "**Marketing Authorization**" shall mean the Regulatory Approvals granted by the relevant Governmental Authority in a jurisdiction of the Territory that entitles the holder thereof to Commercialize the Product in the relevant jurisdiction of the Territory.

1.26 "**Milestone Payment**" has the meaning set forth in Section 5.2(a).

1.27 "**Oragenics Indemnitees**" has the meaning set forth in Section 9.1.

1.28 "**Patents**" means (a) all registered patents and patent applications (including provisional applications), (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, requests for continued examination, confirmations, re-examinations, extensions, supplementary protection certificates and the like of the foregoing, and (c) any foreign or international equivalents of any of the foregoing.

1.29 "**Person**" includes a natural person, partnership, limited partnership, limited liability partnership, syndicate, sole proprietorship, corporation or company (with or without share capital), limited liability company, joint-stock company, trust, unincorporated association, joint venture or other entity or Governmental Authority.

1.30 "**Personnel Assistance**" has the meaning set forth in Section 5.7(b).

1.31 "**Prime Rate**" means the rate of interest, expressed as an annual rate in effect from time to time, as charged by Bank of America from time to time as its prime rate with respect to commercial loans made in US dollars in the United States of America to its commercial borrowers.

1.32 "**Proposed Terms**" has the meaning set forth in Section 12.2.

1.33 "**Regulatory Approval**" means, with respect to the Combination Product in each jurisdiction of the Territory, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to Develop and Commercialize such Combination Product in any part of the Territory.

1.34 "**Regulatory Authority**" means any applicable Governmental Authority or non-governmental pricing and/or reimbursement authority that regulates or otherwise exercises authority with respect to the Development, manufacture or Commercialization of a Combination Product in the Territory.

1.35 "**Research Agreement**" means that certain research agreement entered between the Parties dated February 25, 2022, as amended from time to time.

1.36 "**Study Data**" has the meaning set forth in Section 6.1(b).

1.37 "**Sublicensee**" has the meaning set forth in Section 3.5.

1.38 "**Support Memorandum**" has the meaning set forth in Section 12.2.

1.39 "**Term**" has the meaning set forth in Section 11.1.

1.40 "**Territory**" means worldwide.

1.41 "**Third Party**" means any individual or entity other than the Parties or their respective Affiliates.

1.42 "**Licensed Technology**" means the Inspirevax Patents, Inspirevax Know-How and Inspirevax Improvements.

1.43 "**Royalty Payments**" has the meaning set for in Section 5.3.

1.44 "**Net Sales**" means (a) the Gross Revenues during the term of this Agreement recognized by Oragenics or any of its Affiliates or Sublicensees with respect to sales of the Combination Products, less: (b) (i) shipping costs paid in connection with shipping the Combination Products to customers; (ii) customer credits and returns actually resulting in a refund of amounts paid to Oragenics with respect to rejected, damaged or returned Combination Products; (iii) sales or use taxes collected by Oragenics on behalf of a Governmental Authority and specifically attributable to the Combination Products to the extent included in the Gross Revenues; and (iv) duties, tariffs, customs, government fees, and taxes paid by Oragenics specifically attributable to the import of Combination Products to the extent included in the Gross Revenues or indicated separately in the invoices for the Combination Products, in each case in accordance with Oragenics' generally applicable internal accounting practices and procedures thereto from time to time in effect and consistently applied across product lines and in accordance with IFRS. Notwithstanding the foregoing, sales of the Combination Products by Oragenics to an Affiliate for resale by such Affiliate shall not be counted in "Net Sales" unless such Affiliate is an end-user and "Net Sales" shall be determined, consistently with the definition of "Net Sales," by such Affiliate upon resale.

1.45 "**Net Sublicensing Revenues**" means, with respect to each sublicense of any rights herein, all cash and non-cash consideration (including up-front, milestone, royalty and other similar payments) received from time to time by Oragenics in connection with such sublicense.

ARTICLE 2
GOVERNANCE

2.1 Committee. The Parties will form a joint development committee ("**JDC**") within fifteen (15) days of the Effective Date. The JDC will consist of up to three (3) representatives from each Party with appropriate expertise to serve as members of such Committee and will be chaired by Oragenics. The JDC will meet on a schedule to be agreed upon in good faith by both Parties. The chairperson of the JDC shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting of the JDC, and preparing and issuing minutes of each meeting within fifteen (15) days thereafter. To the extent the meetings are held in person, the Parties will cooperate in good faith to select the meeting location.

2.2 JDC Purpose. The JDC's purpose and responsibility is to: (i) facilitate communication between the Parties; (ii) provide updates to non-clinical and clinical development and regulatory strategy and filings; (iii) identify and resolve differences in approach to non-clinical, clinical and regulatory strategy; (iv) provide Inspirevax the opportunity to review, discuss and propose modifications for use of the Combination Product in toxicology studies and clinical trials and any Investigators Brochure; (v) provide Inspirevax the opportunity to review, discuss and propose modifications to sections of the draft Clinical Study Report that reference the Combination Product prior to finalization and beyond the Term if necessary; and (vi) so long as Oragenics has not assigned this Agreement to, or entered into a sublicense with a Commercialization partner covering all or substantially all of the rights granted under Section 3.1, provide Inspirevax the opportunity to review, discuss and propose modifications to the selection process of manufacturers of any BDX Product and manufacturing agreements solely for the BDX Product. The JDC will also discuss strategies for the long-term commercial supply of the BDX Product. The JDC shall have the obligation to exercise its authority consistent with the respective purpose for the JDC as stated herein and any such decisions shall be made in good faith.

2.3 JDC Decision-Making. In the event that the JDC cannot reach unanimous agreement on a particular matter within thirty (30) days of its initial consideration of such matter, then (A) each Party shall provide written notice of the dispute to its Chief Executive Officer. The Chief Executive Officers of each of the Parties will meet at least once in person or by means of telecommunication (telephone, video, or web conferences) to discuss the dispute and resolve it through good faith negotiations within thirty (30) days after submission of such dispute to the Chief Executive Officers. (B) If the dispute is not resolved within thirty (30) days after submission to the Chief Executive Officer of each Party, the Chief Executive Officer of Oragenics shall have the authority to finally resolve such dispute. Notwithstanding the foregoing, as an alternative to the dispute resolution step outlined in sub-paragraph (B), if the dispute relates solely to a BDX Product and such dispute will affect the value of the BDX Product outside the Agreement, the Chief Executive Officer of Inspirevax shall have the authority to finally resolve the dispute.

ARTICLE 3
License Grants

3.1 License to Oragenics. Subject to the terms and conditions of this Agreement, Inspirevax hereby grants to Oragenics an exclusive license to the Licensed Technology in the Field, with the right to sublicense subject to Section 3.5, to conduct chemistry, manufacturing and control activities, non-clinical and clinical research development and trials, manufacture and distribute the Combination Product in the Field and in the Territory.

3.2 Non-Permitted Use. Oragenics hereby covenants that it shall not, nor shall it permit any Affiliate and, if applicable, licensee or Sublicensee, to use or practice, directly or indirectly, any Licensed Technology for any purposes other than those expressly permitted by this Agreement. Without limiting the generality of the foregoing, Oragenics shall not:

(a) permit any Affiliate, licensee or Sublicensee to conduct chemistry, manufacturing and control activities, non-clinical and clinical research development and trials as regards to BDX Products as a stand-alone product and not as part of a Combination Product; and

(b) sell, distribute or permit any Affiliate, licensee or Sublicensee to sell or distribute any BDX Products as a stand-alone product and not as part of a Combination Product.

3.3 Reserve of Rights. Except for those rights expressly granted to Oragenics hereunder, all rights, express or implicit, with respect to the Licensed Technology belong exclusively to Inspirevax. Without limiting the generality of the foregoing, nothing herein shall limit or restrict Inspirevax's right to directly or indirectly (a) conduct research and development with respect to any product excluding the Combination Product for use in the Field, (b) enhance and improve the BDX Products, as a standalone product or as part of another product excluding the Combination Product for use in the Field (c) manufacture and supply or have manufactured and supplied the BDX Products, as a standalone product or as part of another product excluding the Combination Product for use in the Field (including supply by such CDMO approved hereunder for the manufacture of the BDX Products), or (d) license, market, distribute or sell any BDX Product or any improvement thereof for any indication outside the Field throughout the Territory.

3.4 Rights to Clinical and Regulatory Data and Results. Oragenics shall share the Study Data, together with all related reports, regulatory filings, and communications with and from regulatory authorities, all of which constitutes Confidential Information, with Inspirevax through the JDC under terms of confidentiality. Notwithstanding such confidentiality obligations, Inspirevax shall be permitted, directly or in conjunction with or through partners or other collaborators, to reference the Confidential Information referenced in this paragraph in future regulatory filings to the extent reasonably required. Except for regulatory filings, Inspirevax shall seek prior approval from Oragenics to use the data and results for any purpose, which approval shall not be unreasonably withheld, delayed or conditioned. Inspirevax will have a royalty-free, perpetual, and worldwide right to use such Study Data subject to the limitations above.

3.5 Sublicenses. Any sublicense granted by Oragenics shall (a) be consistent with the terms and conditions of this Agreement and not relieve Oragenics of its obligations hereunder, (b) obligate each Sublicensee to comply with the terms and conditions of this Agreement by agreeing in writing to be bound by substantially the same terms and conditions as Oragenics herein, and (c) automatically terminate upon the termination of this Agreement unless the survival thereof has been expressly approved by Inspirevax in writing. Each Person granted such a sublicense in compliance with the provisions of this Section 3.5 shall be referred to herein as a "**Sublicensee**". Oragenics shall provide Inspirevax with a fully signed non-redacted copy and amendments of each sublicense agreement within ten (10) days after execution (with an official English translation if the sublicense is in any language other than English). Oragenics will be responsible for the performance of any obligations of its sublicensee. Oragenics will pay Inspirevax twenty percent (20%) of all Net Sublicensing Revenues payable by Sublicensees to Oragenics in connection with the sublicensees rights or under the terms of any sublicense agreement. Oragenics shall ensure that each Sublicensee possesses the necessary skills, resources and experience to enable it to perform the obligations sublicensed in accordance with the terms and conditions of this Agreement.

ARTICLE 4
OTHER RIGHTS AND OBLIGATIONS

4.1 Development and Commercialization. Oragenics shall use its best efforts to Develop, manufacture and Commercialize at least one Combination Product throughout the Territory and maximize the returns to each Party under this Agreement. Without limiting the generality of the foregoing, Oragenics shall be solely responsible for the Development of the Combination Products, including, without limitation, conducting and financing of the non-clinical and clinical research and trials as well as the process development of the Combination Product, and the BDX Product as a part thereof, by an appropriate CDMO for use in Phase 2b/3 clinical studies conducted under this Agreement with the review and guidance of the JDC as referenced in ARTICLE 2. Oragenics' financial obligations also includes the costs associated with obtaining a sufficient amount of the BDX Product from Inspirevax to enable Oragenics to perform the research and trials under this Agreement, including, but not limited to the costs for BDX Product to enable the pre-clinical toxicology, clinical development planning and association characterization and stability data. To the extent any Third Party is utilized in the future in relation to testing of the BDX Product, the Parties will work together in good faith to enter into separate agreements with any such Third Party, whether it be an agreement between Oragenics and such Third party or an agreement with Inspirevax and such Third Party with Inspirevax charging amounts paid back to Oragenics.

4.2 BDX Product Cost and Option. Under the terms of the Research Agreement, Oragenics purchased [***] milligrams (protein content of BDX Product as measured by Lowry Assay) of the BDX Product from Inspirevax produced under Good Manufacturing Practice (GMP) standards to enable pre-clinical studies, final product stability studies, GLP toxicology studies, and the clinical studies at a price of [***] per milligram. Prices and inventory for GMP and non-GMP categories of BDX Products as of the Effective Date (the "**Existing Inventory**") are shown in Schedule C. Oragenics will further have a first right of negotiation for the purchase of the Existing Inventory. These purchase prices will give Oragenics access to bulk product stability study data, as well as methods related to the BDX Product, as required. In the event that Oragenics wishes to be supplied quantities of BDX Products in addition to the Existing Inventory following the Effective Date, the Parties will negotiate in good faith the terms and conditions of an agreement for the manufacture and availability of the future lots of the BDX Product.

4.3 Information and Reporting. Oragenics will keep Inspirevax reasonably informed about Oragenics' Development and Commercialization efforts and progress (including those of its Affiliates, licensees, Sublicensees and Third Parties contractor, as applicable) under this Agreement through the JDC as referenced in Article 2. In addition, Oragenics shall provide Inspirevax with a report of the progress of such Development, manufacture and Commercialization on an annual basis on each anniversary of the Effective Date or with such alternative degree of frequency as the Parties may otherwise agree in writing. If upon receiving such a report of progress Inspirevax does not reasonably believe that Oragenics is exercising its best efforts to progress the Development, manufacture, and Commercialization at least one Combination Product, then upon request by Inspirevax, the Parties will meet to discuss Inspirevax's concerns and potential remedies. If, during the six (6) month period following such meeting, there is continued inactivity or failure by Oragenics, its Affiliates or its Sublicensees to progress any Combination Product Development, manufacture and Commercialization program, then Inspirevax shall have the option, upon 60 days' written notice to Oragenics, to convert the licenses granted hereunder to non-exclusive or terminate this Agreement and if BDX does not demonstrate that it is using its best efforts to progress the Development, manufacture and Commercialization at least one Combination Product during such 60 day notice period, then the option selected by Inspirevax in such written notice shall take effect upon the expiration of such 60 day delay.

4.4 Compliance with Law. Each Party shall comply, and Oragenics shall ensure that its Affiliates, licensees, Sublicensees and Third Party contractors comply, with all applicable laws, regulations, and guidelines applicable to the Development and Commercialization of the Combination Product.

4.5 Manufacturing Rights.

(a) So long as Oragenics has not assigned this Agreement to, or entered into a sublicense with a Commercialization partner covering all or substantially all of the rights granted under Section 3.1, the Parties acknowledge that they share a mutual interest in having a single Third Party manufacturer, or one of the Parties, manufacture and supply the BDX Products to the Parties and their Affiliates for Commercialization. Oragenics use of such BDX Products will be limited to being part of the Combination Product in the Field in the Territory.

(b) Each Party's manufacturing agreements with a Third Party manufacturer must, among other things, provide that the other Party will have the right to enter into independent contracts for the supply of the BDX Product with such Third Party manufacturers, on terms and conditions to be negotiated between each manufacturer and the other Party from time to time.

ARTICLE 5
COMPENSATION AND CONTRIBUTIONS

5.1 Signature Fee. Within fifteen (15) days of the Effective Date of the Research License Agreement, Oragenics paid Inspirevax the one lump sum payment of [***] as a signature fee thereunder. Within thirty (30) days of the Effective Date of this Agreement, Oragenics will pay Inspirevax one lump sum payment of [***] as a signature fee hereunder, failing which this Agreement will be null and void, *ab initio*.

5.2 Milestones and Timelines

(a) **Oragenics Milestones and Timelines**. Oragenics will use its best efforts to Develop, manufacture and Commercialize at least one Combination Product and maximize the returns to each Party under this Agreement. Without limiting the generality of the foregoing, Oragenics shall achieve the following in accordance with the timeline set forth below:

(i) First subject enrolled in first study by [***];

(ii) First subject enrolled in Phase 2a Study by [***];

(iii) First subject enrolled Phase 3 registration trial by [***]; and

(iv) First Marketing Approval application submitted by [***].

(b) **Milestone Payments**. Subject to the terms and conditions of this Agreement, upon the first instance of attainment of the milestones as set forth below (unless otherwise provided therein), Oragenics has agreed to make certain milestone payments (each a "**Milestone Payment**" and together "**Milestone Payments**") as set forth in this Section 5.2(b). Oragenics shall immediately advise Inspirevax of the attainment of milestone set forth below and Inspirevax shall thereafter issue an invoice to Oragenics for the applicable Milestone Payment, and the Milestone Payments are each payable in cash by wire transfer to the account specified by Inspirevax within thirty (30) days of the applicable invoice. The Milestone Payments payable by Oragenics to Inspirevax upon achievement of each milestone event are as follows:

(i) a one-time Milestone Payment of [***] upon Oragenics' positive decision on an appropriate nasal-spray device, based on compatibility and characterization of the device for use in the first clinical trial;

(ii) one-time Milestone Payment of [***] upon the first patient dosed in the first Phase 2a clinical trial under this Agreement;

(iii) a one-time Milestone Payment of [***] upon the first patient dosed in the first Phase 2b/3 clinical trial under this Agreement;

(iv) a one-time Milestone Payment of [***] upon a Biologics License Application (BLA) submission for the Combination Product to the United States FDA;

(v) a one-time Milestone Payment of [***] upon the first filing for marketing authorization for the Combination Product outside of the United States;

(vi) additional Milestone Payments of [***] upon each additional filing for marketing authorization for the Combination Product outside of the United States, which is capped at five additional filings (i.e., not to exceed [***] in the aggregate);

(vii) a one-time Milestone Payment of [***] upon the first commercial sale of the Combination Product in the United States;

(viii) a one-time Milestone Payment of [***] upon the first commercial sale of the Combination Product in Europe;

(ix) a one-time Milestone Payment of [***] upon the first commercial sale of the Combination Product outside of the United States and Europe; and

(x) additional Milestone Payments of [***] upon each commercial sale of the Combination Product outside of the United States and Europe, which is capped at five additional countries/regions (i.e., not to exceed [***] in the aggregate).

5.3 Royalty Payments. During the Term of this Agreement, Oragenics shall pay Inspirevax a royalty of (a) [***] of Net Sales until cumulative Gross Revenues resulting from the sales of Combination Products reach a total t[***] and (b) upon the cumulative Gross Revenues resulting from the sales of Combination Products exceeding [***], the royalty payable by Oragenics shall be reduced to [***] of Net Sales (collectively, the "**Royalty Payments**"). Oragenics shall pay to Inspirevax the Royalty Payments due and owing under this Agreement for each calendar quarter ending on March 31, June 30, September 30, and December 31 within thirty (30) days of the end of such calendar quarter. Royalty payments shall be accompanied by a Royalty Report substantially in the form attached as Schedule A.

5.4 Currency; Method of Payment. All payments due hereunder shall be made in US Dollars by direct transfer to the bank account notified to Oragenics by Inspirevax from time to time. When applicable, any amounts which require conversion to US dollars hereunder, shall be converted based on the average of the daily 2:15 pm (CET) spot rate published by the OANDA (www.oanda.com) for the respective currency and for the given period.

5.5 Interest. Any and all amounts payable pursuant to this Agreement, including, without limitation, the Royalty Payments and Milestone Payments, and which are outstanding at any time in whole or in part beyond the delay provided for payment shall bear interest at an annual rate equal to the Prime Rate from time to time plus 4%, calculated daily and payable monthly in arrears on the last day of each and every month, with interest on all overdue interest at the same rate and calculated and payable in the same manner.

5.6 Audit.

(a) Oragenics shall, at its own expense and in accordance with IFRS, prepare and maintain complete and accurate records and books of account containing all information required for the computation and verification of the Net Sales and Royalty Payments and shall maintain such records for a period of five (5) years after the last day of the Term (or such longer period as may be required by applicable laws).

(b) Oragenics shall, upon reasonable request, permit an internal representative or an independent certified public accountant in each case selected and paid for by Inspirevax to have free access during regular business hours to Oragenics' offices, files, books and account and other records relating to the previous five (5) calendar years, for the purpose of verifying and auditing the information to be provided by Oragenics to Inspirevax pursuant to Section 5.3, each Royalty Statement and the calculation of the Net Sales and Royalty Payments.

(c) The cost of such inspection, examination or audit shall be borne by Inspirevax unless such inspection, examination or audit reflects an underpayment of five percent (5%) or more in the Royalty Payments remitted and reported by Oragenics and the actual Royalty Payments due pursuant to Section 5.3, in which case such costs shall be paid by Oragenics upon presentation of the applicable invoices.

(d) In the event of any such underpayment, Oragenics shall within ten (10) business days pay to Inspirevax any unremitted amounts of Royalty Payments with interest as stipulated in Section 5.5, calculated from the 30th day following the date on which same was due and payable.

5.7 Inspirevax Contributions. In consideration of Oragenics' payments to Inspirevax, Inspirevax agrees to the following contributions:

(a) Upon request by Oragenics, Inspirevax agrees to provide sufficient and reasonable regulatory support for the BDX Product to enable a Phase 1/2a clinical trial to be conducted in the United States of America as well as Phase 2b/3 clinical trials.

(b) Inspirevax agrees to provide support from appropriate Inspirevax personnel with sufficient expertise in non-clinical, clinical, regulatory and chemistry, manufacturing and controls aspects of the BDX Product ("**Personnel Assistance**") to enable Phase 1/2a and Phase 2b/3 clinical trials to be conducted with the BDX Product, and to provide BDX Product-specific information required to regulatory filings for the BDX Product the whole, at an hourly rate of [***] for executive management personnel and [***] for management personnel. Inspirevax agrees that the following actions will not be considered as Personnel Assistance: (i) participation time of any Inspirevax personnel on the JDC; (ii) processing of any Milestone Payments; and (iii) time spent by Inspirevax personnel on general business activities related to this Agreement outside of providing the specific expertise described in this Section 5.7(b).

ARTICLE 6
Intellectual Property

6.1 Ownership.

(a) Subject to the license granted under Section 3.1, all rights in the BDX Product and the Licensed Technology shall remain with Inspirevax. All rights, including any and all intellectual property rights, in any invention conceived, reduced to practice or developed by the Parties, jointly, or by a party alone, pursuant to this Agreement and solely arising from, or solely related to the BDX Product, the Licensed Technology or the Delivery Improvements (collectively, the "**Inspirevax Improvements**") will be owned by Inspirevax. The Inspirevax Improvements will be part of the Licensed Technology as of their time of conception. Oragenics' will have the right to use the Delivery Improvements only in connection with a Combination Product. For the avoidance of doubt, Delivery Improvements do not include the Antigen or the Combination Product.

(b) Oragenics shall own all data and results generated from the research and clinical and non-clinical trials performed under this Agreement in relation to a Combination Product (the "**Study Data**"), excluding, for avoidance of doubt, any data arising from CMC activities solely relating to the BDX Products and research and clinical and non-clinical trials solely relating to the Delivery Improvements. Further as between the parties, all the rights, including any and all intellectual property rights, in any invention conceived, reduced to practice or developed by the Parties, jointly, or by a Party alone, pursuant to this Agreement and solely arising from, or solely related to the Combination Product or the Antigen, but excluding, for the avoidance of doubt, the Inspirevax Improvements, will be owned by Oragenics ("**Oragenics IP**").

(c) All rights, technology, and intellectual property (i) owned by Oragenics or licensed from a Third Party by Oragenics as of the Effective Date, or (ii) thereafter developed by Oragenics outside the scope of this Agreement, shall be owned by and remain the property of Oragenics; provided however that Oragenics hereby assign, and shall cause to assign its Affiliates, licensees, Sublicensees and Third Party contractors, to Inspirevax, all rights, title and interest, including any invention and other intellectual property right, if any, developed or reduced to practice under the Research Agreement, solely arising from, or solely related to: the BDX Product, the Licensed Technology or the Delivery Improvements.

(d) All rights, technology, and intellectual property (i) owned by Inspirevax or licensed from a Third Party by Inspirevax as of the Effective Date, or (ii) thereafter developed by Inspirevax outside the scope of this Agreement, shall be owned by and remain the property of Inspirevax.

(e) In all other instances, to the extent a Party solely conceives, reduces to practice or develops an invention under this Agreement, that Party will own all rights, including any and all intellectual property rights, in such invention. To the extent the Parties jointly conceive, reduce to practice or develop an invention under the definitive agreement, such inventions shall be jointly owned by the Parties.

(f) The Parties will cooperate together in good faith on any additional measures that may need to be taken for any Party to protect and document its intellectual property rights and ownership.

(g) Inspirevax will control the application, prosecution and maintenance of the Inspirevax Patents and Inspirevax Improvements, at Inspirevax's expense.

(h) Oragenics will control the application, prosecution, and maintenance of the Patent(s) relating to the Oragenics IP, at Oragenics' expense. Inspirevax will have the right to review any patent application regarding the Oragenics IP sufficiently in advance of the filing for the purpose of restricting the terms of a filing that includes unpublished information, Confidential Information, or know-how related, in whole or in part, to the BDX Product, the Licensed Technology, or the Inspirevax Improvements.

ARTICLE 7
CONFIDENTIALITY

7.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that it shall keep confidential and shall not publish or otherwise disclose and shall not use for any purpose other than as provided for in this Agreement any Confidential Information disclosed to it by the other Party pursuant to this Agreement, except to the extent that the receiving Party can demonstrate by competent evidence that specific Confidential Information:

(a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement;

(d) was disclosed to the receiving Party, other than under an obligation of confidentiality to a Third Party, by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or

(e) was independently discovered or developed by the receiving Party without the use of Confidential Information belonging to the disclosing Party, as documented by the receiving Party's written records.

The foregoing non-use and non-disclosure obligation shall continue (i) indefinitely, for all Confidential Information that qualifies as a trade secret under applicable law; or (ii) for the Term of this Agreement and for seven (7) years thereafter, in all other cases.

7.2 Authorized Disclosure. Notwithstanding the limitations in this ARTICLE 7, either Party may disclose the Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following instances:

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

(b) to regulatory authorities in order to seek or obtain approval to conduct clinical trials, or to gain regulatory approval, of the Combination Product or any products being developed by Inspirevax or its other licensees and/or channel partners or collaborators, provided that the Party making such disclosure (i) provides the other Party with reasonable opportunity to review any such disclosure in advance and to suggest redactions or other means of limiting the disclosure of such other Party's Confidential Information and (ii) does not unreasonably reject any such suggestions;

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

(d) disclosure on a need-to-know basis to Affiliates, licensees, Sublicensees, employees, consultants or agents who agree to be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this ARTICLE 7.

7.3 Terms of the Agreement. Each Party shall treat the terms of this Agreement as the Confidential Information of the other Party.

ARTICLE 8
Representations And Warranties

8.1 Representations and Warranties of Oragenics. Oragenics hereby represents and warrants to Inspirevax that, as of the Effective Date:

(a) **Corporate Power**. Oragenics is duly organized and validly existing under the laws of Florida and has corporate full power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) **Due Authorization**. Oragenics is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on Oragenics' behalf has been duly authorized to do so by all requisite corporate action.

(c) **Binding Agreement**. This Agreement is a legal and valid obligation binding upon Oragenics and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by Oragenics does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. Oragenics is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

(d) **Additional Intellectual Property Representations**.

(i) Oragenics has entered into agreements with each of its current and former officers, employees and consultants involved in research and development under the Research Agreement or this Agreement, providing for, to the extent permitted by law, an assignment of their rights, with title and ownership to patents, patent applications, trade secrets and inventions conceived, their rights, with title and ownership to patents, patent applications, trade secrets and inventions conceived, developed, reduced to practice by such person, solely or jointly with other of such persons, during the period of employment by Inspirevax (except where the failure to have entered into such an agreement would not have a material adverse effect on the rights granted to Inspirevax herein), and Oragenics is not aware that any of its employees or consultants is in material violation thereof; and

(ii) To Oragenics' knowledge, no employee of Oragenics is the subject of any claim or proceeding involving a violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, non-disclosure agreement or any restrictive covenant to or with a former employer (A) where the basis of such violation relates to such employee's employment with Oragenics or actions undertaken by the employee while employed with Oragenics and (B) where such violation is relevant to the use of the Antigen in the Field.

8.2 Representations and Warranties of Inspirevax. Inspirevax hereby represents and warrants to Oragenics that, as of the Effective Date:

(a) **Corporate Power**. Inspirevax is duly organized and validly existing under the federal laws of Canada and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof.

(b) **Due Authorization**. Inspirevax is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person executing this Agreement on Inspirevax's behalf has been duly authorized to do so by all requisite corporate action.

(c) **Binding Agreement**. This Agreement is a legal and valid obligation binding upon Inspirevax and enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, insolvency, reorganization, arrangement, moratorium or other similar laws affecting creditors' rights, and subject to general equity principles and to limitations on availability of equitable relief, including specific performance. The execution, delivery and performance of this Agreement by Inspirevax does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound. Inspirevax is aware of no action, suit or inquiry or investigation instituted by any governmental agency which questions or threatens the validity of this Agreement.

(d) **Additional Intellectual Property Representations**.

(i) Subject to the assignment under Section 6.1(c), Inspirevax possesses sufficient rights to enable it to grant all rights and licenses it purports to grant to Oragenics with respect to the Licensed Technologies under this Agreement;

(ii) Inspirevax has not granted, and during the Term Inspirevax will not grant, any right or license, to any Third Party under the Licensed Technology that conflicts with the rights or licenses granted or to be granted to Oragenics hereunder;

(iii) To Inspirevax's knowledge, there is no pending litigation, and Inspirevax has not received any written notice of any claims or litigation, seeking to invalidate or otherwise challenge the Licensed Technology or Inspirevax's rights therein;

(iv) To Inspirevax's knowledge, none of the Licensed Technology is subject to any pending re-examination, opposition, interference or litigation proceedings;

(v) All of the Inspirevax Patents have been filed and prosecuted in accordance with all applicable laws and have been maintained, with all applicable fees with respect thereto (to the extent such fees have come due) having been paid;

(vi) Inspirevax has entered into agreements with each of its current and former officers, employees and consultants involved in research and development work, including development of the BDX Product and Licensed Technology, providing for, to the extent permitted by law, an assignment of their rights, with title and ownership to patents, patent applications, trade secrets and inventions conceived, developed, reduced to practice by such person, solely or jointly with other of such persons, during the period of employment by Inspirevax (except where the failure to have entered into such an agreement would not have a material adverse effect on the rights granted to Oragenics herein), and Inspirevax is not aware that any of its employees or consultants is in material violation thereof;

(vii) To Inspirevax's knowledge, there is no infringement, misappropriation or violation by third parties of the Licensed Technology in the Field;

(viii) There is no pending or, to Inspirevax's knowledge, threatened action, suit, proceeding or claim by others against Inspirevax that Inspirevax infringes, misappropriates or otherwise violates any intellectual property or other proprietary rights of others in connection with the use of the Licensed Technology, and Inspirevax has not received any written notice of such claim;

(ix) To Inspirevax's knowledge, no employee of Inspirevax is the subject of any claim or proceeding involving a violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, non-disclosure agreement or any restrictive covenant to or with a former employer (A) where the basis of such violation relates to such employee's employment with Inspirevax or actions undertaken by the employee while employed with Inspirevax and (B) where such violation is relevant to the use of the Licensed Technology in the Field;

(x) To Inspirevax's knowledge, none of the Inspirevax Patents have been adjudged invalid or unenforceable by a court of competent jurisdiction or applicable government agency, in whole or in part, and there is no pending or, to Inspirevax's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Inspirevax Patents; and

(xi) Except as otherwise disclosed in writing to Oragenics, to Inspirevax's knowledge it: (A) is in material compliance with all statutes, rules or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of the BDX Product ("**Applicable Laws**"); (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the United States Food and Drug Administration (the "**FDA**") or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"), which would not, individually or in the aggregate, result in a material adverse effect; (C) possesses all material Authorizations necessary for the operation of its business as described in the Field and such Authorizations are valid and in full force and effect and Inspirevax is not in material violation of any term of any such Authorizations; and (D) since January 1, 2011, (1) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit investigation or proceeding; (2) has not received notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; (3) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission); and (4) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to Inspirevax's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

Except, in each of (ix) through (xii), for any instances which would not, individually or in the aggregate, result in a material adverse effect on the rights granted to Oragenics hereunder or Inspirevax's ability to perform its obligations hereunder.

(e) **Manufacture of Existing Inventory**. The Existing Inventory (i) has been manufactured in compliance with the current good manufacturing practice and standards contemplated by the *Food and Drugs Act* (Canada) in force at the time of manufacture of the relevant BDX Products, but solely to the extent such Existing Inventory is identified as GMP-grade product in **Schedule C** hereto; and (ii) will conform at the time of delivery to Oragenics to the applicable specifications for each BDX Product set forth in **Schedule D** hereto.

8.3 Warranty Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES PROVIDED IN THIS ARTICLE 8, EACH PARTY HEREBY DISCLAIMS ANY AND ALL OTHER WARRANTIES, EITHER EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY WARRANTIES OF TITLE, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

8.4 Limitation of Liability. IN NO EVENT SHALL INSPIREVAX, ORAGENICS OR ANY OF THEIR RESPECTIVE AFFILIATES OR ANY OF THEIR RESPECTIVE DIRECTORS, OFFICERS, EMPLOYEES, AND AGENTS BE LIABLE TO THE OTHER PARTY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND ARISING IN ANY WAY OUT OF THIS AGREEMENT OR THE LICENSE OR RIGHTS GRANTED HEREUNDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, INCLUDING WITHOUT LIMITATION ECONOMIC DAMAGES OR INJURY TO PROPERTY OR LOST PROFITS, REGARDLESS OF WHETHER SUCH PARTY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW OF THE POSSIBILITY OF THE FOREGOING.

ARTICLE 9
INDEMNIFICATION

9.1 Indemnification by Inspirevax. Inspirevax agrees to indemnify, hold harmless, and defend Oragenics and its Affiliates and their respective directors, officers, employees, and agents (collectively, the "**Oragenics Indemnitees**") from and against any and all liabilities, damages, costs, expenses, or losses (including reasonable legal expenses and attorneys' fees) (collectively, "**Losses**") resulting from any claims, suits, actions, demands, or other proceedings brought by a Third Party (collectively, "**Claims**") to the extent arising from (a) the negligence or willful misconduct of Inspirevax or any of its Affiliates, or their respective employees or agents; or (b) breach by Inspirevax of any representation, warranty or covenant in this Agreement. Notwithstanding the foregoing, Inspirevax shall not have any obligation to indemnify the Oragenics Indemnitees to the extent that a Claim arises from (i) the negligence or willful misconduct of Oragenics or any of its Affiliates, licensees, or Sublicensees, or their respective employees or agents; or (ii) a breach by Oragenics of a representation, warranty, or covenant of this Agreement.

9.2 Indemnification by Oragenics. Oragenics agrees to indemnify, hold harmless, and defend Inspirevax and its Affiliates and their respective directors, officers, employees, and agents (collectively, the "**Inspirevax Indemnitees**") from and against any Losses resulting from Claims, to the extent arising from any of the following: (a) the negligence or willful misconduct of Oragenics or any of its Affiliates or their respective employees or agents; or (b) breach by Oragenics of any material representation, warranty or covenant in this Agreement; (c) any alleged Third Party infringement or misappropriation claim of intellectual property in relation to the Development, manufacture or Commercialization of a Combination Product; or (d) the use of a Combination Product. Notwithstanding the foregoing, Oragenics shall not have any obligation to indemnify the Inspirevax Indemnitees to the extent that a Claim arises from (i) the negligence or willful misconduct of Inspirevax or any of its Affiliates, or their respective employees or agents; or (ii) a breach by Inspirevax of a representation, warranty, or covenant of this Agreement.

9.3 Control of Defense. As a condition precedent to any indemnification obligations hereunder, any entity entitled to indemnification under this ARTICLE 9 shall give written notice to the indemnifying Party of any Claims that may be subject to indemnification, promptly after learning of such Claim. If such Claim falls within the scope of the indemnification obligations of this ARTICLE 9, then the indemnifying Party shall assume the defense of such Claim with counsel reasonably satisfactory to the indemnified Party. The indemnified Party shall cooperate with the indemnifying Party in such defense. The indemnified Party may, at its option and expense, be represented by counsel of its choice in any action or proceeding with respect to such Claim. The indemnifying Party shall not be liable for any litigation costs or expenses incurred by the indemnified Party without the indemnifying Party's written consent, such consent not to be unreasonably withheld. The indemnifying Party shall not settle any such Claim if such settlement (a) does not fully and unconditionally release the indemnified Party from all liability relating thereto or (b) adversely impacts the exercise of the rights granted to the indemnified Party under this Agreement, unless the indemnified Party otherwise agrees in writing.

ARTICLE 10
INSURANCE

10.1 Insurance. During the Term, Oragenics shall carry and maintain at its sole expense, comprehensive general liability insurance (including but not limited to commercial general liability and products liability) and professional liability insurance and such other coverage as may be reasonably recommended by Inspirevax's insurers from time to time. All such insurance shall (a) be issued by insurers having an AM Best (A-) or higher rating as acceptable by Inspirevax and (b) name Inspirevax as an additional insured with a full waiver of subrogation in favour of Inspirevax. Oragenics shall provide Inspirevax at least thirty (30) calendar days advance notice of any cancellation, termination, or material alteration of said insurance policies. Oragenics shall deliver to Inspirevax, prior to the execution of this Agreement and at any other time upon reasonable request, an insurer or insurer's agent signed certificates of insurance as well as all other documents which Inspirevax may reasonably require, as evidence that policies providing such coverage and limits of insurance are in full force and effect. If any such insurance is on a "claims made basis", such insurance must be maintained for six (6) years following termination of this Agreement for any reason whatsoever.

10.2 Failure to Comply. Neither Oragenics' failure to comply with any or all of the insurance provisions of this Agreement nor the failure to secure endorsements on the policies as may be necessary to carry out the terms and provision of this Agreement shall be construed to limit or relieve Oragenics of any of its obligations under this Agreement including, without limitation, those set out in Section 10.1.

ARTICLE 11
TERM; TERMINATION

11.1 Term. Unless earlier terminated pursuant to the terms hereof, the term of this Agreement shall commence upon the Effective Date and will remain in effect, on a jurisdiction-by-jurisdiction basis, until the latest of (a) the last date on which the Combination Product is covered by a valid patent claim, (b) the expiration of regulatory exclusivity which provides market exclusivity for the Combination Product in such jurisdiction of the Territory, and (c) twenty (20) years from the first commercial sale of the Combination Product in such jurisdiction in the Territory (the "**Term**").

11.2 Termination for Material Breach. Either Party shall have the right to terminate this Agreement upon written notice to the other Party if the other Party commits any material breach of this Agreement that such breaching Party fails to cure within sixty (60) days following written notice from the nonbreaching Party specifying such breach.

11.3 Termination Without Material Breach. In addition to Termination for Material Breach pursuant to Section 11.2, Oragenics shall have the right to voluntarily terminate this Agreement by providing thirty (30) days written notice to Inspirevax. Upon the effective date of such termination notice, Inspirevax will use commercially reasonable efforts to avoid additional expenses and/or minimize expenses, where such expenses are non-cancellable.

11.4 Effects of Termination. In the event of termination of this Agreement pursuant to Section 11.2 (Termination for Material Breach) or Section 11.3 (Termination Without Material Breach), the following shall apply:

(a) **Termination of License**. All rights and licenses granted by Inspirevax to Oragenics under this Agreement shall terminate and shall revert to Inspirevax without further action by either Inspirevax or Oragenics.

(b) **Reports and Payments**. Final Royalty Reports in accordance with Section 5.3 shall be submitted by Oragenics and all payments, including without limitation any Royalty Payments and Milestone Payments, accrued or due to Inspirevax as of the effective date of termination of the Agreement shall become immediately payable.

(c) **Regulatory Filings**. Following termination and at the written request of Inspirevax, Oragenics shall promptly assign to Inspirevax, and will provide full copies of, all regulatory approvals and regulatory filings that relate specifically to the research and clinical and non-clinical trial conducted under this Agreement. Oragenics shall also take such actions and execute such other instruments, assignments and documents as may be necessary to effect the transfer of rights thereunder to Inspirevax.

(d) **Third-Party Agreements**. At Inspirevax's written request, Oragenics shall promptly provide to Inspirevax copies of all ongoing Third-Party agreements under which Oragenics or its Affiliates entered into to conduct the research and clinical and non-clinical trials under this Agreement. At Inspirevax's written request, and to the extent reasonably possible, the Parties will work together in good faith to assign, or if need be sublicense, any such Third-Party agreements to Inspirevax. Thereafter Inspirevax shall be fully responsible for all obligations due for its actions under the sublicensed or assigned Third Party agreements.

(e) **CMC**. In the event that this Agreement is terminated prior to Commercialization and unless Inspirevax elects to continue the CMC development of the BDX Product, Oragenics will be responsible for all costs relating to the termination of the Combination Product Phase 2b/3 CMC development including the CDMO termination costs and any non-refundable reservation fees. If Inspirevax elects to continue CMC development of the BDX Product with its own funding and the CDMO's activities are not terminated, there will be no termination costs to be paid by either party. For avoidance of doubt, in such case, Inspirevax will not have to compensate Oragenics for the non-refundable reservation fees.

(f) **Further Assistance**. Oragenics shall provide, at its own costs and expense, any other assistance or take any other actions, in each case, reasonably requested by Inspirevax as necessary to transfer to Inspirevax the Development, manufacture and Commercialization of the Combination Products in the Territory, and will execute all documents as may be reasonably requested by Licensors in order to give effect to this Section 11.3.

(g) **Confidential Information**. Each Party shall promptly return, or at the other Party's written request destroy, any Confidential Information of the other Party in such Party's possession or control at the time of termination; provided, however, that each Party shall be permitted to retain (i) a single copy of each item of Confidential Information of the other Party in its confidential legal files for the sole purpose of monitoring and enforcing its compliance with ARTICLE 7, (ii) Confidential Information of the other Party that is maintained as archive copies on the recipient Party's disaster recovery and/or information technology backup systems. The recipient of Confidential Information shall continue to be bound by the terms and conditions of this Agreement with respect to any such Confidential Information retained in accordance with this Section 11.4(g).

11.5 Surviving Obligations. Termination or expiration of this Agreement shall not affect any rights of either Party arising out of any event or occurrence prior to termination, including, without limitation, any obligation of Oragenics to pay any amount which became due and payable under the terms and conditions of this Agreement prior to expiration or such termination. The following portions of this Agreement shall survive termination or expiration of this Agreement: Sections 3.3, 11.4 and 11.5; ARTICLE 6, ARTICLE 7, ARTICLE 9, ARTICLE 10, ARTICLE 12, and ARTICLE 13; and any relevant definitions in ARTICLE 1.

ARTICLE 12
DISPUTE RESOLUTION

12.1 Disputes. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. In the event of any disputes, controversies or differences which may arise between the Parties out of or in relation to or in connection with this Agreement (other than disputes arising from the JDC as referenced in Section 2.3), including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, then upon the request of either Party by written notice, the Parties agree to meet and discuss in good faith a possible resolution thereof, which good faith efforts shall include at least one in-person meeting between the Chief Executive Officers of each Party. If the matter is not resolved within thirty (30) days following the written request for discussions, either Party may then invoke the provisions of Section 12.2.

12.2 Arbitration. Any dispute, controversy, difference or claim which may arise between the Parties out of or in relation to or in connection with this Agreement (including, without limitation, arising out of or relating to the validity, construction, interpretation, enforceability, breach, performance, application or termination of this Agreement) that is not resolved pursuant to Section 12.1 shall, subject to such Section, be settled by binding "baseball arbitration" as follows. Either Party, following the end of the thirty (30) day period referenced in Section 12.1, may refer such issue to arbitration by submitting a written notice of such request to the other Party. Promptly following receipt of such notice, the Parties shall meet and discuss in good faith and seek to agree on an arbitrator to resolve the issue, which arbitrator shall be neutral and independent of both Parties and all of their respective Affiliates, shall have significant experience and expertise in licensing agreements in the pharmaceutical and biotechnology industries, and shall have some experience in mediating or arbitrating issues relating to such agreements. If the Parties cannot agree on a single arbitrator within fifteen (15) days of request by a Party for arbitration, then each Party shall select an arbitrator meeting the foregoing criteria and the two (2) arbitrators so selected shall select within ten (10) days of their appointment a third arbitrator meeting the foregoing criteria. Within fifteen (15) days after an arbitrator(s) is selected (in the case of the three-person panel, when the third arbitrator is selected), each Party will deliver to both the arbitrator(s) and the other Party a detailed written proposal setting forth its proposed terms for the resolution for the matter at issue (the "**Proposed Terms**" of the Party) and a memorandum (the "**Support Memorandum**") in support thereof. The Parties will also provide the arbitrator(s) a copy of this Agreement, as it may be amended at such time. Within fifteen (15) days after receipt of the other Party's Proposed Terms and Support Memorandum, each Party may submit to the arbitrator(s) (with a copy to the other Party) a response to the other Party's Support Memorandum. Neither Party may have any other communications (either written or oral) with the arbitrator(s) other than for the sole purpose of engaging the arbitrator or as expressly permitted in this Section 12.2; provided that, the arbitrator(s) may convene a hearing if the arbitrator(s) so chooses to ask questions of the Parties and hear oral argument and discussion regarding each Party's Proposed Terms. Within sixty (60) days after the arbitrator's appointment, the arbitrator(s) will select one of the two Proposed Terms (without modification) provided by the Parties that he or she believes is most consistent with the intention underlying and agreed principles set forth in this Agreement. The decision of the arbitrator(s) shall be final, binding, and unappealable. For clarity, the arbitrator(s) must select as the only method to resolve the matter at issue one of the two sets of Proposed Terms, and may not combine elements of both Proposed Terms or award any other relief or take any other action.

12.3 Governing Law. This Agreement shall be governed by and construed under the substantive laws of the State of Delaware, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction.

12.4 Award. Any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 12.2 shall be promptly paid in United States dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by law, be charged against the losing Party. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this ARTICLE 12, and agrees that, subject to the United States Federal Arbitration Act, 9 U.S.C. §§ 1-16, judgment may be entered upon the final award in the United States District Court located in Delaware and that other courts may award full faith and credit to such judgment in order to enforce such award. The award shall include interest from the date of any damages incurred for breach of the Agreement, and from the date of the award until paid in full, at a rate fixed by the arbitrator(s). With respect to money damages, nothing contained herein shall be construed to permit the arbitrator(s) or any court or any other forum to award consequential, incidental, special, punitive or exemplary damages. By entering into this agreement to arbitrate, the Parties expressly waive any claim for consequential, incidental, special, punitive or exemplary damages. The only damages recoverable under this Agreement are direct compensatory damages.

12.5 Costs. Each Party shall bear its own legal fees. The arbitrator(s) shall assess his or her costs, fees and expenses against the Party losing the arbitration.

12.6 Injunctive Relief. Nothing in this ARTICLE 12 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the status quo pending the arbitration proceeding. Specifically, the Parties agree that a material breach by either Party of its obligations in Section 3.2 or ARTICLE 7 of this Agreement may cause irreparable harm to the other Party, for which damages may not be an adequate remedy. Therefore, in addition to its rights and remedies otherwise available at law, including, without limitation, the recovery of damages for breach of this Agreement, upon an adequate showing of material breach of such Section 3.2 or ARTICLE 7, and without further proof of irreparable harm other than this acknowledgement, such non-breaching Party shall be entitled to seek (a) immediate equitable relief, specifically including, but not limited to, both interim and permanent restraining orders and injunctions, without bond, and (b) such other and further equitable relief as the court may deem proper under the circumstances. For the avoidance of doubt, nothing in this Section 12.6 shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 11.2.

12.7 Confidentiality. The arbitration proceeding shall be confidential, and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any dispute submitted to arbitration, and the award, shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by applicable law.

12.8 Survivability. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.

12.9 Jurisdiction. For the purposes of this ARTICLE 12, the Parties acknowledge their diversity and agree to accept the jurisdiction of the United States District Court located in Delaware for the purposes of enforcing or appealing any awards entered pursuant to this ARTICLE 12 and for enforcing the agreements reflected in this ARTICLE 12 and agree not to commence any action, suit or proceeding related thereto except in such courts.

ARTICLE 13
General Provisions

13.1 Use of Name. No right, express or implied, is granted by this Agreement to either Party to publicly use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement, except that (a) either Party may use the name of the other Party as required by regulations and in any press releases that both Parties have agreed upon in writing.

13.2 LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS PARAGRAPH IS INTENDED TO LIMIT OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER ARTICLE 9, OR DAMAGES AVAILABLE FOR BREACHES OF THE OBLIGATIONS SET FORTH IN ARTICLE 7.

13.3 Independent Parties. Neither Party is the employee or legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party. This Agreement shall not constitute, create, or in any way be interpreted as a joint venture, partnership, or business organization of any kind.

13.4 Notice. All notices, including notices of address change, required or permitted to be given under this Agreement shall be in writing and deemed to have been given when delivered if personally delivered or sent by facsimile (provided that the party providing such notice promptly confirms receipt of such transmission with the other party by telephone), on the business day after dispatch if sent by a nationally-recognized overnight courier and on the third business day following the date of mailing if sent by certified mail, postage prepaid, return receipt requested, or on the same business day, if sent by email during business hours. All such communications shall be sent to the address or facsimile number set forth below (or any updated addresses or facsimile number communicated to the other Party in writing):

If to Inspirevax:	Inspirevax Inc. 46 rue de Saint-Tropez Kirkland, Québec Canada, H9J 2K6 Attention: Joseph Zimmermann Fax: (438) 404-4147 Email: joseph@inspirevax.com
If to Oragenics:	Oragenics, Inc. 4902 Eisenhower Blvd. Suite 125 Tampa, FL 33634 Attention: Chief Executive Officer Fax: (813) 286-7904 Email: kmurphy@oragenics.com

with a copy to: Shumaker, Loop & Kendrick, LLP
101 E. Kennedy Blvd., Suite 2800
Tampa, FL 33602
Attention: Mark Catchur, Esq.
Fax: (813) 229-1660
Email: mcatchur@shumaker.com

13.5 Severability. In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.

13.6 Waiver. Any waiver (express or implied) by either Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

13.7 Entire Agreement; Amendment. This Agreement, including any exhibits attached hereto, constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement (including the Research Agreement, the term sheet entered into between the Parties dated December 22, 2022 and any prior confidentiality agreement between the Parties). All information of Inspirevax or Oragenics to be kept confidential by the other Party under any prior confidentiality agreement, as of the Effective Date, shall be maintained as Confidential Information by such other Party under the obligations set forth in ARTICLE 7 of this Agreement. This Agreement may not be modified or amended except in a writing signed by a duly authorized representative of each Party.

13.8 Non-assignability; Binding on Successors. Any attempted assignment of the rights or delegation of the obligations under this Agreement shall be void without the prior written consent of the non-assigning or non-delegating Party; provided, however, that either Party may assign its rights or delegate its obligations under this Agreement without such consent (a) to an Affiliate of such Party or (b) to its successor in interest in connection with any merger, acquisition, consolidation, corporate reorganization, or similar transaction, or sale of all or substantially all of its assets, provided that such assignee agrees in writing to assume and be bound by the assignor's obligations under this Agreement. This Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and permitted assigns of the Parties.

13.9 Currency. Unless otherwise expressly provided herein, all references to "dollars" or "$" herein shall refer to United States dollars.

13.10 Force Majeure. Neither Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed because rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental regulation, fire, flood, labor difficulties, civil disorder, acts of terrorism and acts of God, provided that the Party experiencing the delay promptly notifies the other Party of the delay.

13.11 No Other Licenses. Neither Party grants to the other Party any rights or licenses in or to any intellectual property, whether by implication, estoppel, or otherwise, except to the extent expressly provided for under this Agreement.

13.12 Legal Compliance. The Parties shall review in good faith and cooperate in taking such actions to ensure compliance of this Agreement with all applicable laws.

13.13 Counterparts. This Agreement may be executed in any number of counterparts (including by facsimile, PDF, or other means of electronic communication), each of which taken together will constitute one and the same instrument, and any of the Parties hereto may execute this Agreement by signing any such counterpart.

13.14 GSK License The Parties agree that all terms and conditions set forth in this Agreement should be consistent with GSK License. In the event of conflict between the terms of this Agreement and the GSK License, the terms of the GSK License prevails.

13.15 NRC License The Parties agree that all terms and conditions set forth in this Agreement should be consistent with the July 26, 2021 Oragenics and National Research Council of Canada license agreement (NRC License). In the event of conflict between the terms of this Agreement and the NRC License, the terms of the NRC License prevails.

13.16 NIH License The Parties agree that all terms and conditions set forth in this Agreement should be consistent with the March 12, 2020 National Institutes of Health license agreement (NIH License). In the event of conflict between the terms of this Agreement and the NIH License, the terms of the NIH License prevails.

13.17 Additional Targets. For a period of [***] days following the Effective Date (the "**Exclusivity Period**"), Inspirevax agrees to exclusively negotiate with Oragenics the terms and conditions of an option agreement to license the development rights to the BDX Products as regards the [***], [***] and [***] as additional vaccine targets (the "**Additional Targets**"). Such option agreement would provide that, if the option is exercised, option exercise payments, milestones, and royalties would be included as a supplement to this Agreement. During the Exclusivity Period, Inspirevax agrees to not enter into a letter of intent, memorandum of understanding, agreement in principle, commitment or agreement with a person other than Oragenics relating to grant of license rights to the BDX Products in relation to the Additional Targets.

[Remainder of page intentionally left blank.]

In Witness Whereof, the Parties hereto have duly executed this Research License Agreement.

INSPIREVAX INC.		**ORAGENICS, INC.**	
By:	*/s/ Joseph Zimmermann*	By:	*/s/ Kimberly M. Murphy*
Name:	Joseph Zimmermann	Name:	Kimberly M. Murphy
Title:	President & CEO	Title:	President & CEO

[Signature Page to Commercial License Agreement]

Schedule A
Royalty Report

Reporting Information
Reporting Period From: / / To: / /
Prepared By
Payment Date and Method
Services

Royalty Computation

Sales Vol. 1st Mo.	Sales Vol. 1st Mo.	Sales Vol. 1st Mo.	Total Gross Sales*	Less Deductions	Net Sales	Royalty Rate	Royalty Amount	Total Royalty (USD)
							Total:	

Itemized Deductions

Explanation of Deduction (Permitted deductions are listed in the License Agreement. Also note any unusual occurrences that affected royalty amounts during this period.)	Deduction Amount ($)
Total Deduction:	

Sublicense Income

Sublicense Name	Sublicense Income	Sublicense Rate (%)	Sublicense Amount ($)	Conversion Rate (%)	Total Royalty in US ($)
				Total:	
				Total Payment Due	

Schedule B
Inspirevax Patents

Compositions and Methods for Activating Innate and Allergic Immunity

Patent Number	Expiration Date	Status
US 8,173,140	22 October 2024	In good standing in US
US 8,709,447	22 October 2024	In good standing in US
US 9,433,672	22 October 2024	In good standing in US
EP 1,689,433	22 October 2024	In good standing in Belgium, Germany, Spain, France, Great Britain and Italy
EP 2,174,665	22 October 2024	In good standing in Belgium, Germany, Spain, France, Great Britain, Holland and Italy
JP 4,966,661	22 October 2024	In good standing in Japan

Schedule C
BDX Products

BDX Products are BDX300 and BDX301

BDX300 and BDX301 are mucosal vaccine adjuvant formulations comprised of outer membrane proteins and lipo-oligosaccharide from *Neisseria meningitidis* and other bacterial components from this source which are manufactured using methods described in US Patent 9,433,672 and with proprietary know-how that is the intellectual property of Inspirevax.

Existing Inventory and Pricing for BDX Products

Item	Description	Amount in Inventory	Cost	Comments
1	*Neisseria meningitidis* GMP Cell Paste (Lot MENB2167-F-2019012C-01)	[***] bottles	[***] per bottle	- Each bottle contains approximately [***] mL concentrated *N. meningitidis* cell paste. - Full scale production utilizes [***] bottles per lot.
2	BDX301 mucosal adjuvant Bulk Drug Substance – (non-GMP) Engineering Lot (X0001DSPE001)	[***] mg	[***]/mg	
3	BDX301 mucosal adjuvant Bulk Drug Substance – (non-GMP) Lot (X0001DSPC001)	[***] mg	[***]/mg	- This lot was not released for clinical use due to in process deviation. QC testing values at time of production were within specification. Consequently, this material may be suitable for formulation development activities.
4	BDX301 mucosal adjuvant Bulk Drug Substance - GMP Lot (X0001DSPC002)	[***] mg	[***]/mg	- In addition to this amount, Oragenics owns [***] mg of material that is in storage at Biodextris and has already been purchased from Inspirevax.

NOTES:

- The costs for items 1,2 and 3 are for material currently in Inspirevax' inventory and reflect a reduction in price due to recovery of costs from prior activities.
- Pricing is in US Dollars.
- Inventory as of February 8, 2023.
- Pricing for BDX Products other than the Existing Inventory will be subject to a separate agreement between the parties to be negotiated in good faith.

Schedule D
BDX Products Specifications

[***]

[***]

[***] 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.

National Research Council Canada | Conseil national de recherches Canada

Amendment 5 to
Technology License Agreement

BUSINESS CONFIDENTIAL – PROTECTED B

THIS IS AN AMENDING AGREEMENT (hereinafter referred to as the "**Amendment # 5**")

BETWEEN: **NATIONAL RESEARCH COUNCIL OF CANADA** (called **"NRC"**)
a Departmental Corporation"
forming part of the Government of Canada, which corporation was created by Act of Parliament, R.S.C. 1985, c. N-15
whose head office address is: 1200 Montreal Road, Ottawa, Ontario K1A 0R6 Canada

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

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

AND: **ORAGENICS, INC.** (called the **"Licensee"**)
a corporation under the laws of the state of Florida, the United States of America
whose address is: 4902 Eisenhower Boulevard – Suite 125- Tampa, Florida, 33634, U.S.A.
Contact: Janet Huffman – Email: **jhuffman@oragenics.com**

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

WHEREAS the Parties entered into a Technology License Agreement signed by NRC on July 26, 2021 [NRC ref. # A-0039781], which was amended four times by virtue of written and signed amendments (together referred to as the **"Original Agreement"**) by which NRC granted a license for internal R&D and Commercial purposes to the Licensee**.**

WHEREAS the Parties agreed in Amendment 4 [NRC ref. #A-0043676] to add and include Additional Protocols and Reagents to be considered as part of the Original Agreement.

WHEREAS the NRC transferred the Additional Protocols and Reagents to the Licensee and invoiced the Additional Protocol Fees.

WHEREAS the Licensee informed the NRC that they are not willing to sustain the use of the Additional Protocols and Reagents.

WHEREAS the Parties agree to revert back to the originally agreed upon terms and conditions prior to the execution of Amendment 4.

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

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

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

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

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

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

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

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

BUSINESS CONFIDENTIAL – PROTECTED B

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

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

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

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

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

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

8. The Licensee hereby agrees to return all Additional Protocols, Reagents, and all information related thereto transferred from the NRC to the Licensee and Contractor(s) under Amendment 4, to the NRC within thirty (30) days of signing Amendment # 5.

9. The Licensee hereby confirms that the Licensee and Contractor(s) have ceased any and all use of the Additional Protocols and Reagents and shall continue to abide by the Licensee's Obligations of Confidentiality in the Original Agreement.

10. Upon receipt of the Additional Protocols, Reagents, and all information related thereto, the NRC hereby agrees to cancel the issued invoice for the Additional Protocol Fees.

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

SIGNED by the **Licensee** at Tampa, Florida, U.S.A.

ORAGENICS, INC.

April 6, 2023

Date:

Per: */s/ Janet Huffman*
Janet Huffman - CFO

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

NATIONAL RESEARCH COUNCIL OF CANADA

Date: April 3, 2023

Per: */s/ Susan Twine*
Susan Twine

Per:

Exhibit 31.1

CERTIFICATION

I, Kimberly Murphy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated this 12th day of May 2023

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

Exhibit 31.2

CERTIFICATION

I, Janet Huffman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated this 12th day of May 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 March 31, 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: May 12, 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 March 31, 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: May 12, 2023