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

FORM 10-Q

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

For the quarterly period ended September 30, 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 November 7, 2023, there were 2,569,385 shares of Common Stock, $0.001 par value, outstanding.

Note Regarding Reverse Stock Splits

We filed an amendment to our Amended and Restated Articles of Incorporation with the Secretary of the State of Florida to effect a reverse split of our authorized and outstanding common stock at a ratio of one for sixty (1 for 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.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 5,766,644	$ 11,426,785
Other receivables	35,104	—
Prepaid expenses and other current assets	2,012,344	2,844,798
Total current assets	7,814,092	14,271,583
Property and equipment, net	52,399	121,062
Operating lease right-of-use assets	24,337	347,440
Deposits	8,600	17,940
Total assets	$ 7,899,428	$ 14,758,025
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 884,350	$ 1,124,197
Short-term notes payable	493,420	267,640
Operating lease liabilities - Current	24,337	204,447
Total current liabilities	1,402,107	1,596,284
Long-term liabilities:		
Operating lease liabilities - Long Term	—	152,439
Total long-term liabilities	—	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 September 30, 2023 and December 31, 2022, respectively	1,592,723	1,592,723
Common stock, $0.001 par value; 4,166,666 shares authorized;2,569,385 and 2,024,657 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2,549	2,025
Additional paid-in capital	198,372,874	196,977,071
Accumulated deficit	(193,470,825)	(185,562,517)
Total shareholders' equity	6,497,321	13,009,302
Total liabilities and shareholders' equity	$ 7,899,428	$ 14,758,025

The accompanying notes to the condensed consolidated financial statements are an integral part of these statements.

Oragenics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Grant revenue	$ 7,466	$ 86,047	$ 37,653	$ 131,521
Operating expenses:				
Research and development	769,350	2,777,068	4,448,623	8,660,761
General and administrative	1,332,562	1,215,498	3,697,609	3,592,361
Total operating expenses	2,101,912	3,992,566	8,146,232	12,253,122
Loss from operations	(2,094,446)	(3,906,519)	(8,108,579)	(12,121,601)
Other income (expense):				
Interest income	50,613	41,634	171,768	68,909
Interest expense	(14,170)	(5,228)	(18,360)	(9,290)
Other income	45,118	—	46,863	11,333
Total other income, net	81,561	36,406	200,271	70,952
Loss before income taxes	(2,012,885)	(3,870,113)	(7,908,308)	(12,050,649)
Income tax benefit	—	—	—	—
Net loss	$ (2,012,885)	$ (3,870,113)	$ (7,908,308)	$ (12,050,649)
Basic and diluted net loss per share	$ (0.85)	$ (1.99)	$ (3.70)	$ (6.21)
Weighted average shares used to compute basic and diluted net loss per share	2,356,065	1,945,747	2,136,340	1,941,858

The accompanying notes to the condensed consolidated financial statements are an integral part of these statements.

Oragenics, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity
(Unaudited)

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2022	2,024,657	$ 2,025	9,467,000	$ 1,592,723	$ 196,977,071	$ (185,562,517)	$ 13,009,302
Compensation expense relating to option issuances	—	—	—	—	79,966	—	79,966
Net loss	—	—	—	—	—	(2,844,837)	(2,844,837)
Balances at March 31, 2023	2,024,657	2,025	9,467,000	1,592,723	197,057,037	(188,407,354)	10,244,431
Compensation expense relating to option issuances	—	—	—	—	63,628	—	63,628
Net loss	—	—	—	—	—	(3,050,586)	(3,050,586)
Balances at June 30, 2023	2,024,657	$ 2,025	9,467,000	$ 1,592,723	$ 197,120,665	$ (191,457,940)	$ 7,257,473
Compensation expense relating to option issuances	—	—	—	—	(1,591)	—	(1,591)
Compensation expense relating to restricted stock issuances	140,000	120			404,396		404,516
Common stock issued in private placement	404,728	404			849,404		849,808
Net loss	—	—	—	—	—	(2,012,885)	(2,012,885)
Balances at September 30, 2023	2,569,385	$ 2,549	$ 9,467,000	1,592,723	198,372,874	(193,470825)	$ 6,497,321

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2021	2,002,946	$ 2,003	16,017,000	$ 2,656,713	$ 195,101,611	$ (171,274,128)	$ 26,486,199
Compensation expense relating to option issuances	—	—	—	—	90,247	—	90,247
Net loss	—	—	—	—	—	(4,590,993)	(4,590,993)
Balances at March 31, 2022	2,002,946	$ 2,003	16,017,000	$ 2,656,713	$ 195,191,858	$ (175,865,121)	$ 21,985,453
Compensation expense relating to option issuances	—	—	—	—	278,988	—	278,988
Net loss	—	—	—	—	—	(3,589,543)	(3,589,543)
Balances at June 30, 2022	2,002,946	$ 2,003	16,017,000	$ 2,656,713	$ 195,470,846	$ (179,454,664)	$ 18,674,898
Compensation expense relating to option issuances	—	—	—	—	468,545	—	468,545
Conversion of Series A preferred stock to common stock	400,001	400	(4,000,000)	(415,169)	414,769	—	—
Conversion of Series B preferred stock to common stock	510,002	510	(2,550,000)	(648,821)	648,311	—	—
Net loss	—	—	—	—	—	(3,870,113)	(3,870,113)
Balances at September 30, 2022	2,912,949	$ 2,913	$ 9,467,000	1,592,723	197,002,471	(183,324,777)	$ 15,273,330

The accompanying notes to the condensed consolidated financial statements are an integral part of these statements.

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

	For the Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (7,908,308)	$ (12,050,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	27,391	31,594
Gain on sale of property and equipment	(22,443)	(10,964)
Stock-based compensation expense	546,519	837,780
Changes in operating assets and liabilities:		
Other receivables	(35,104)	6,987
Operating Lease Right of Use Assets	323,103	—
Prepaid expenses and other current assets	1,443,563	(1,608,905)
Deposits	9,340	—
Accounts payable and accrued expenses	(572,396)	(1,490)
Net cash used in operating activities	(6,188,335)	(12,795,647)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	63,715	12,000
Purchase of property and equipment	—	(124,081)
Net cash provided by (used in) investing activities	63,715	(112,081)
Cash flows from financing activities:		
Payments on short-term notes payable	(385,329)	(406,921)
Proceeds from issuance of common stock from private placement	849,808	—
Net cash provided by (used in) financing activities	464,479	(406,921)
Net decrease in cash and cash equivalents	(5,660,141)	(13,314,649)
Cash and cash equivalents at beginning of period	11,426,785	27,265,703
Cash and cash equivalents at end of period	$ 5,766,644	$ 13,951,054
Supplemental disclosure of cash flow information:		
Interest paid	$ 3,347	$ 9,290
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	$ 611,109	$ 528,429
Value of Series A preferred stock converted into common stock	$ —	$ 415,169
Value of Series B preferred stock converted into common stock	$ —	$ 648,821
Par Value of common stock issued in connection with Series A Preferred Stock Conversion	$ —	$ 400
Par Value of common stock issued in connection with Series B Preferred Stock Conversion	$ —	$ 510

The accompanying notes to the condensed consolidated financial statements are an integral part of these statements.

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

1. Organization

Oragenics, Inc. (the "Company" or "we", or "our") is focused on the development of intranasal drug delivery platforms dedicated to fighting infectious diseases. Our lead product is an intranasal vaccine candidate (NT-CoV2-1) to combat the novel Severe Acute Respiratory Syndrome coronavirus ("SARS-CoV-2").

On October 4, 2023 we announced the signing of a definitive agreement with Odyssey Health, Inc. to acquire certain proprietary assets related to neurological drug therapies including their proprietary formulation and nasal delivery system. The assets include drug candidates for treating mild traumatic brain injury, also known as concussion, and for treating Niemann Pick Disease Type C. The transaction is expected to close at the end of the fourth quarter of 2023, subject to the satisfaction of various closing conditions, of which there can be no assurances.

We have made several changes to reduce expenses and conserve cash resources to prioritize our vaccine product's research and development until additional capital can be obtained. Recently, in September of 2023, we terminated our lease for the building where some of our research and development activities for its lantibiotic program were undertaken. Currently research and development activities related to the lantibiotic program are inactive. We intend to evaluate alternative opportunities for this program moving forward as we continue to strengthen our focus and expertise on our intranasal drug delivery platform and drug candidates.

2. Basis of Presentation

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

Going Concern Consideration

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 $7,908,308 and used cash of $6,188,335 in its operating activities during the nine months ended September 30, 2023. As of September 30, 2023, the Company had an accumulated deficit of ($193,470,825).

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes its working capital at September 30, 2023 will be sufficient to meet the business objectives as presently structured only through the first quarter of 2024. As such, there is substantial doubt that we can continue as a going concern beyond that date. As a result, the Company has implemented certain cost-saving initiatives, including the termination of its lease of the building in Alachua, Florida where some of the research and development for the lantibiotic program was undertaken. In addition to the termination of the lease, the Company has also eliminated certain staff positions and transitioned Dr. Martin Handfield from an employee of the Company to a consultant through an hourly basis consulting agreement.

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.

On October 4, 2023 the Company entered into an Asset Purchase Agreement ("Purchase Agreement") with Odyssey Health, Inc., a Nevada corporation ("Odyssey"). Per the terms of the Purchase Agreement, the Company agreed to purchase and assume, and Odyssey agreed to sell and assign, certain assets and certain liabilities related to treating brain related illnesses and diseases (the "Purchased Assets"). Although the Company believes that the Purchased Assets could provide positive synergies to strengthen the Company's current intranasal drug delivery platform, the Company cannot be certain that the acquisition of this proprietary neurological drug therapy and technology will be successful.

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 nine months ended September 30, 2023, that have had, or are expected to have, a material impact on our consolidated financial statements.

Use of Estimates

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

Reclassification

Certain prior year amounts have been reclassified for consistency with the current year presentation. These reclassifications had no effect on the reported results of operations.

Stock-Based Payment Arrangements

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

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.

Net Loss Per Share

During all periods presented, the Company had securities outstanding that could potentially dilute basic earnings per share in the future but were excluded from the computation of diluted net loss per share, as their effect would have been antidilutive because the Company reported a net loss for all periods presented. All references to common stock for the comparative three and nine-month periods ended September 30, 2022, have been adjusted to reflect the effect of the reverse split. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

Concentrations

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company maintains cash accounts in commercial banks, which may, at times, exceed federally insured limits. The Company has not experienced any losses in such accounts. The Company believes there is a minimal credit risk on cash and cash equivalents. Cash and cash equivalents could be adversely impacted, including the loss of uninsured deposits and other uninsured financial assets, if one or more of the financial institutions in which the Company holds its cash or cash equivalents fails or is subject to other adverse conditions in the financial or credit markets.

Grant Revenue

Grant revenues are derived from a small business innovation research grant in the amount of $250,000 ("Computer-aided Design for Improved Lantibiotics"). 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 statements of operations. The grant recognition was completed as of July 31, 2023, any remaining grant revenue from the program was recognized in the three-month period ended September 30, 2023.

4. Prepaid Expense and Other Current Assets

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

	September 30, 2023	December 31, 2022
Prepaid research and development expense	$ 1,468,936	$ 2,471,809
Prepaid insurance	535,908	372,989
Other prepaid costs	7,500	-
Total accounts payable and accrued expenses	$ 2,012,344	$ 2,844,798

5. Accounts Payable and Accrued Expenses

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

	September 30, 2023	**December 31, 2022**
Accounts payable trade	$ 808,935	$ 246,690
Accrued expenses	45,276	812,861
Professional fees	-	31,101
Vacation	30,139	33,545
Total accounts payable and accrued expenses	$ 884,350	$ 1,124,197

6. Short-Term Notes Payable

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

	September 30, 2023	**December 31, 2022**
Directors' and officers' liability insurance financing of $611,109 and $528,429 due in monthly installments of $64,316 and $54,366 including principal and interest at 9.55% and 5.34% through May 24, 2024 and May 24, 2023, respectively	$ 493,420	$ 267,640

The Company's policy renewals were completed in July of 2023.

7. Shareholders' Equity

Common Stock

Reverse Stock Split

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

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

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. However, the Company did not issue any shares of common stock under its ATM with Ladenburg during the three and nine-month periods ended September 30, 2023.

Other Share Issuances

On August 4, 2023 the Company entered into a Securities Purchase Agreement (the "Agreement") to issue in a private placement (the "Offering") an aggregate of i) 404,728 shares of the Company's common stock, $0.01 par value (the "Common Stock"), and ii) 404,728 of Series E Mirroring Preferred Stock (the" Series E Preferred Stock"). The rights and preferences of the Series E Preferred Stock are set forth in the Certificate of Designation that was filed with the Secretary of State for the State of Florida. The private placement generated gross proceeds of $850,000.

Preferred Stock

Issuance of Series E Preferred Stock

Related to the August 4, 2023 Offering an aggregate of 404,728 shares of Series E Mirroring Preferred Stock were issued in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act"), and Regulation D promulgated thereunder and, have not been registered under the Act, or applicable state securities laws. Accordingly, the Common Stock and Series E Preferred Stock may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

The Company is proposing an amendment to its Amended and Restated Articles of Incorporation, in connection with the Company's annual meeting of shareholders, to effect an increase in the shares of Common Stock the Company is authorized to issue from 4,166,666 shares of Common Stock to 350,000,000 shares of Common Stock. The Series E Preferred Stock has super voting rights on the proposed amendment equal to 2,500 votes per share of Series E Preferred Stock. Pursuant to the Purchase Agreement, the investors have agreed to vote in favor of the amendment. The Series E Preferred will vote in favor and against the amendment in the same proportion as the shares of common stock cast at the annual meeting in favor and against the amendment. In the event that the amendment is effected, each share of Series E Mirroring Preferred Stock shall be automatically transferred to the Company and cancelled for no consideration on the effective date of the amendment with no action on behalf of the holder and such shares shall resume the status of authorized but unissued shares of preferred stock and shall no longer be designated as Series E Mirroring Preferred Stock. In the event that the amendment is not approved, the 404,728 shares of Series E Mirroring Preferred Stock will remain issued and outstanding.

8. Warrants

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

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

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

9. Stock Compensation Plan

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value [1]
Outstanding at December 31, 2022	139,090	$ 41.49	7.85	$
Granted	9,000	$ 3.84	-	$
Exercised	—	$ —	—	$
Forfeited	(36,100)	$ 53.23	-	$
Outstanding at September 30, 2023	111,990	$ 38.30	7.50	$
Exercisable at September 30, 2023	95,148	$ 43.46	7.20	$

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock option awards and the closing market price of our common stock as of December 31, 2022 and September 30, 2023, respectively.

On February 25, 2022, the Company held its 2021 Annual Meeting. At the 2021 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 September 30, 2023, an aggregate of 111,990 shares of common stock are covered by outstanding option awards and 51,449 shares of common stock are available for future awards under the 2021 Incentive Plan.

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

Total compensation cost related to stock options was approximately a $1,600 benefit due to forfeitures and $278,988 for the three months ended September 30, 2023 and 2022, respectively. Total compensation cost related to stock options was approximately $142,003 and $369,235 for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, there was approximately $126,896 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of less than one year.

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

Total compensation cost related to restricted stock awards was approximately $404,396 for the three and nine months ended September 30, 2023. There was no restricted stock award cost related for the three and nine months ended September 30, 2022. As of September 30, 2023, there was approximately $67,392 of unrecognized compensation costs related to restricted stock awards, which is expected to be recognized over a weighted average period of less than six months.

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

	Nine-months Ended September 30, 2023
Risk free interest rate	4.0%
Expected volatility of common stock	143.0%
Dividend yield	0.0%
Expected life of options	10 years

10. License and Royalty Agreements

Lantern Bioworks Royalty

On September 26, 2023 the Company completed the sale and transfer of certain materials and data to Lantern Bioworks ("Lantern") pursuant to a Material Transfer Agreement (the "Agreement"). Under the terms of the Agreement, the Company transferred certain biological samples/strains (referred to as "Samples") and associated data, including but not limited to testing, assays, and stability data (the "Data") (collectively, the "Transferred Assets") to Lantern. In exchange for the transfer, Lantern i) paid to the Company $50,000 in cash (the "Funds"); and ii) granted the Company an option to purchase 1,000,000 shares of Lantern equity for total consideration of $1.00, and iii) agreed to pay the Company a royalty equal to ten percent (10%) of the net income derived from any products developed from the Transferred Assets. The duration of the royalty payments spans a ten (10) year term. The agreement also contained other standard terms and conditions. As of September 30, 2023 the Company has not exercised the $1 purchase option.

Inspirevax License

On February 23, 2023, the Company entered into a Commercial License Agreement (the "Inspirevax 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 Inspirevax License Agreement an upfront signing fee and to certain milestone payment obligations.

NRC License

On July 26, 2021, the Company entered into a non-exclusive Technology License Agreement (the "NRC License Agreement") with the National Research Council of Canada ("NRC") pursuant to which the NRC grants to the Company a license to use NRC's inventions, patents, trade secrets, know-how, copyright, biological material, designs, and/or technical information created by or on behalf of the NRC (the "NRC Technologies") relating to the derivatives of CHO $^{2353\ TM}$ Cell Line listed in the NRC License Agreement (the "Stable Cells") to: (i) make, research, and develop SARS-CoV-2 spike protein manufactured by a Stable Cell (the "Drug Substance*")* within Canada, Australia, the United Kingdom, the European Union and the United States (U.S.) (collectively the "Territory"); (ii) file regulatory approval, export and sell the final formulation of the Drug Substance ("Products") and (iii) engage contractors to use the Stable Cells to make Drug Substance or Products on behalf of the Company to be used and sold, worldwide, by the Company. The NRC License Agreement was subsequently amended in September and December of 2021, again in February and July of 2022, and most recently in April of 2023. Consolidated the amendments included the following changes to the NRC License Agreement i) to include the Delta and Omicron variants, ii) provided terms to broaden the non-exclusive field of use to include all diseases caused by coronaviruses and any genetic variants thereof, additionally iii) removed certain protocols and reagents from the NRC License Agreement, and iv) included amendments to remove any license fees owed by the Company to the NRC related to the returned protocols and reagents.

11. Commitments and Contingencies

Inspirevax

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

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

Unless terminated earlier, the Inspirevax 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 Inspirevax 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 Inspirevax License Agreement, provided that if the defaulting party cures the breach within sixty (60) days after the notice is given, the Inspirevax License Agreement shall continue in full force and effect. The Inspirevax License Agreement contains customary confidentiality obligations.

NRC License

In April of 2023 the NRC License Agreement was amended to remove any license fees owed by the Company to the NRC related to the returned protocols and reagents

Three-Way Collaborative Agreement

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

12. 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 for the three and nine-months ended September 30, 2023 was approximately $162,320 and $276,493 respectively. The lease was terminated on September 13, 2023 and in connection therewith the Company paid a termination fee equal to approximately nine-months rent.

Corporate Office-Tampa. In November of 2016, the Company entered into an amendment for the leased office space for corporate personnel located in Tampa, FL. The amended lease is for approximately 2,207 square feet. The lease period for the office space was thirty-six months commencing on March 1, 2017. The Company entered into amendments extending the term of the lease in November 2019 and August 2022. The lease expires on February 29, 2024. Lease payments are $5,906 per month inclusive of insurance, taxes, and utilities. Total rent expense for the three and nine-months ended September 30, 2023 was $17,719 and $51,855, respectively.

	September 30, 2023	December 31, 2022
Weighted Average Remaining Lease Term In Years		
Operating leases	0.42	1.72
Weighted Average Discount Rate		
Operating leases	6.24%	5.78%

Maturities of operating lease liabilities are as follows:

Year ended December 31:	
2023	14,831
2024	9,887
Total	$ 24,718
Less: effect of discounting	(381)
Present value of lease liabilities	$ 24,337

The cost component of operating leases is as follows:

	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Operating lease cost	$ 174,442	$ 114,259
Short-term lease cost	-	1,965
Total lease cost	$ 174,442	$ 116,224

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

	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 178,339	$ 117,350

13. Subsequent Events

Asset Purchase Agreement

On October 4, 2023, the Company entered into an Asset Purchase Agreement (the "APA") with Odyssey Health, Inc., f/k/a Odyssey Group International, Inc., a Nevada corporation ("Odyssey"). Pursuant to the APA, the Company has agreed to purchase and assume, and Odyssey has agreed to sell and assign, certain assets and certain liabilities related to a segment of Odyssey's business focused on developing medical products that treat brain related illnesses and diseases (the "Purchased Assets") in exchange for (i) $1,000,000 in cash and 8,000,000 shares of convertible Series F Preferred Stock ("Series F Preferred Stock"), on and subject to the terms and conditions set forth therein (such transaction, the "Odyssey Asset Purchase"). The Purchased Assets include drug candidates for treating mild traumatic brain injury (mTBI), also known as concussion, and for treating Niemann Pick Disease Type C (NPC), as well as Odyssey's proprietary powder formulation and its nasal delivery device.

The cash is to be paid in two installments: $500,000 upon the execution of the APA and $500,000 upon the earlier of (a) the closing of the Purchase Agreement (the "Closing), (b) within three (3) business days after the date that Odyssey has obtained its stockholders' approval approving the Odyssey Asset Purchase and (c) immediately upon the Company's wrongful termination of the Purchase Agreement in breach of the Purchase Agreement. At the Closing, the Company will issue 8,000,000 shares of Series F Preferred Stock to Odyssey.

The closing of the Odyssey Asset Purchase is expected to close at the end of the fourth quarter of 2023, subject to the satisfaction of customary closing conditions, of which there can be no assurance. The closing conditions include: (1) Odyssey shall have obtained all required consents to the Odyssey Asset Purchase; (2) Odyssey shall have obtained its shareholders' approval to the Odyssey Asset Purchase; (3) the Company's shareholders shall have approved (a) the increase in the Company's authorized Common Stock from 4,166,666 to 350,000,000 and (b) the conversion of the Series F Preferred Stock into Common Stock; (4) no material adverse change shall have occurred to the Purchased Assets; (5) the Company must have at least $5,000,000 in cash at Closing; and (6) the Company must have completed its due diligence of the Purchased Assets to its satisfaction.

The Purchase Agreement also includes customary representations, warranties, and covenants. The Purchase agreement also contains indemnification rights for each of the Company and Odyssey for breaches of representations, warranties, and covenants.

Although the Company believes that the Purchased Assets could provide positive synergies to strengthen the Company's current intranasal drug delivery platform, the Company cannot be certain that the acquisition of this proprietary neurological drug therapy and technology will be successful. See, "Risk Factors."

Addition to Board of Directors

On October 4, 2023 the Company's Board of Directors approved an increase in the size of the board of directors from five (5) to seven (7) individuals. Following the increase in the size of the Company's board of directors, the Board of Directors appointed Mr. Bruce Cassidy and Mr. John Gandolfo to the Company's board.

Messrs. Cassidy and Gandolfo were chosen to serve as members of the Company's board due their extensive leadership and business experience, as well as their service and experience on other boards of directors for companies in the life sciences and pharmaceutical industries as well as in the entertainment and media industries. In connection with the appointment of Messrs. Cassidy and Gandolfo to the Company's board of directors and pursuant to the Company's 2021 Plan as applied to new, non-employee directors, the Company also granted to each of Messrs. Cassidy and Gandolfo stock options to purchase 5,102 shares of the Company's common stock at an exercise price per share equal to the fair market value per share on the date before they became directors, which shares will immediately vest and be exercisable for ten years, subject to early termination under the terms of the Plan.

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, including, but not limited to, statements regarding the ability of Odyssey and the Company to successfully close the their Asset Purchase Agreement; the ability of the Company to timely and successfully achieve the anticipated benefits of acquiring the Odyssey assets; and the Company's future performance, business prospects, events and product development plans. 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" located below and 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. We are focused on the development of intranasal drug delivery platforms dedicated to fighting infectious diseases.

Currently, 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.

We have made several changes to reduce expenses and conserve cash resources to prioritize our vaccine product's research and development until additional capital can be obtained. Recently, in September of 2023, we terminated our lease for the building where some of our research and development activities for our lantibiotic program were undertaken. We intend to evaluate alternative opportunities for this program moving forward as we continue to strengthen our focus and expertise on our intranasal drug delivery platform and drug candidates.

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

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

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

Coronaviruses are a family of viruses that can lead to upper-respiratory infections in humans. Recent clinical reports also suggest that the SARS-CoV-2 virus can affect other body-systems, including the nervous, cardiovascular, gastrointestinal and renal systems. Among the recent iterations of coronaviruses to move from animal to human carriers is SARS-CoV-2, which, beginning in Wuhan, China, in late 2019, caused a global pandemic due to its rapid spread and the relatively high mortality rate (as compared to the seasonal influenza). As of November 2, 2023, the World Health Organization's estimates indicate the number of worldwide COVID-19 confirmed cases have exceeded 771 million and the number of deaths directly attributed to COVID-19 have exceeded 6.9 million. Pfizer/BioNTech received FDA approval for their COVID-19 vaccines in August of 2021 and the Moderna vaccine in January 2022. In July of 2022, the FDA granted EUA for the Novavax COVID-19 vaccine. FDA granted EUA for Janssen's COVID-19 vaccine in February of 2021 and revoked the EUA on June 1, 2023. On April 18, 2023, FDA amended the EUA of both Moderna and Pfizer/BioNTech Bivalent (Original and Omicron BA.4/BA.5 strains) to be used for all doses administered to individuals six months of age and older. Available vaccines have reduced the rates of hospitalization and death due to COVID-19 in vaccinated individuals, but the transmission levels even in vaccinated individuals has allowed SARS-CoV-2 variants to continue to circulate. We believe given the size of the worldwide spread of COVID-19 that even with additional vaccines available, there will be demand for the highly differentiated NT-CoV2-1 vaccine, once development is successfully completed. We intend to combine the research, patent applications and biological materials covered by our NIAID license and with our NRC license and our existing clinical research and manufacturing capabilities to respond rapidly to this ongoing, global, public health issue. We believe our NT-CoV2-1 vaccine holds the possibility of playing an important role in addressing this issue.

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

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

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

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

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

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

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

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

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

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

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

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

Through assessment of a variety of factors including our pre-clinical testing to date, the expected benefits noted above, evolving variants and available vaccines in use, we determined to focus our development efforts on the intranasal delivery of our vaccine product candidate, NT-CoV2-1, which we believe is more highly differentiated than the currently available and late-stage COVID-19 vaccines. We are currently evaluating formulation options and considering regulatory pathways to advance the program. In connection therewith, we are strategically assessing multiple opportunities inclusive of further regulatory guidance and requirements, and the potential implications thereof.

We expect to use our currently available cash resources to continue to advance the development of NT-CoV2-1 through IND-enabling studies. The ability to file an IND application in the United States and/or a Clinical Trial Application in Canada and thereafter commence a Phase 1 clinical study is contingent upon the receipt of additional funding, including non-dilutive government grant funding which we continue to pursue, or partnering or out-licensing opportunities.

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

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

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

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

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

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

The timing of the filing of an IND regarding any future lantibiotic candidate is subject to our having sufficient available human, material and financing capital, which includes research subjects, both animal and human, given all of our anticipated needs and expected requirements in connection with our ongoing research and development initiatives. Based upon the current funding we expect to reduce our focus on the identification of new potential product lantibiotic candidates, efficient and cost-effective improvements in the manufacturing processes and pre-clinical studies required to support a first in human Phase 1 clinical study until such time as we raise additional capital.

In October 2021, we were awarded a small business innovation research grant in the amount of $250,000 (“Computer-aided Design for Improved Lantibiotics”, R41GM136034) for the Company’s continued research and development of lantibiotics, including its collaborative program with the Biomolecular Sciences Institute at Florida International University (FIU). The grant provides the Company with funding to develop novel lantibiotics for the treatment of ESKAPE pathogens (defined as *Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter spp.*). The grant and its related work were completed in July of 2023.

We have made several changes to reduce cash used in operations until additional capital can be obtained. In September of 2023, the Company terminated its lease for the building where some of the research and development activities for its lantibiotic program were undertaken. The closing of the laboratory was part of the Company’s continued focus on preserving cash resources while it seeks additional funding through various mechanisms including but not limited to; sublicensing arrangements, joint venturing or partnering, sales or rights to technology, government grants and public or private financings, through selling additional debt or equity securities or obtaining a line of credit or other loan. Currently, research and development activities related to the lantibiotic program are inactive. We intend to evaluate opportunities for this program moving forward as we continue to strengthen our focus and expertise on our intranasal drug delivery platform and drug candidates.

On September 29, 2023 the Company signed a partnership with Lantern Bioworks, marked by the formalization of a materials transfer agreement for replacement therapy assets. This milestone follows rigorous testing and validation of Oragenics’ biological samples, which are poised to potentially revolutionize dental caries prevention by replacing harmful bacterial strains with non-pathogenic counterparts. Under the agreement, Oragenics received a cash payment of $50,000 along with an opportunity to buy one million shares in Lantern Bioworks. Lantern Bioworks has also committed to pay the Company a 10% royalty on the net income generated from any products arising from the transferred assets. The royalty payments will span a 10-year-term.

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”).

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

Our Business Development Strategy

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

As part of the Company's efforts to preserve cash resources, focus on the development of our NT-CoV2-1 product candidate, and anticipated, although uncertain, expansion into neurological drug therapies, in September of 2023 the Company closed its facility in Alachua Florida where some of the work related to the lantibiotics program was performed. Until the Company can secure additional capital and determine an alternative solution to continue the lantibiotics research and development the program will remain paused.

Recent Developments

On October 5, 2023, we announced the signing of a definitive agreement with Odyssey Health, Inc. (OTCQB: ODYY) ("Odyssey"). Per the terms of the agreement, subject to various closing conditions, we anticipate acquiring Odyssey's assets (OPN-002) related to its proprietary neurological drug therapies and technologies for treating mild traumatic brain injury (mTBI), also known as concussion and for treating Niemann Pick Disease Type C (NPC), as well as Odyssey's proprietary powder formulation and it nasal delivery device. We may not be able to successfully close this transaction. See, Risk Factors.

About Mild Traumatic Brain Injury (mTBI)

Concussions are an unmet medical need that affect millions worldwide. Repetitive concussions can increase the risk of developing Chronic Traumatic Encephalopathy (CTE) and other neuropsychiatric disorders. It is estimated that 5 million concussions occur in the U.S. annually and that as many as 50% go unreported. The worldwide incidence of concussion is estimated at 69 million. The global market for concussion treatment was valued at $6.9 billion in 2020 and is forecast to reach $8.9 billion by 2027, according to Grandview Research. Common settings for concussion include contact sports, military training and operations, motor vehicle accidents, children at play and elderly assistive-living facilities due to falls.

About ONP-002

ONP-002 is a fully synthetic, non-naturally occurring neurosteroid being developed to treat mTBI (concussion). In preclinical studies, the drug demonstrated equivalent or better neuroprotective effects compared with related neurosteroids. Animal models of concussion showed the drug reduces the behavioral pathology associated with brain injury symptoms such as memory impairment, anxiety and motor/sensory performance. Additionally, ONP-002 is lipophilic and can easily cross the blood-brain barrier to rapidly eliminate swelling, oxidative stress and inflammation while restoring proper blood flow.

About Niemann-Pick Type C Disease

Niemann-Pick Type C (NPC) disease is a rare neurodegenerative genetic disorder characterized by the inability of cells to metabolize and properly transport cholesterol and other lipids, leading to the abnormal accumulation in various bodily tissues, including brain tissue. The NPC market is expected to grow from $128 million in 2022 to $188 million in 2031 across the U.S., Germany and U.K.

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 $4,286,302 and $8,660,761 for the nine-months ended September 30, 2023 and 2022, respectively. Our research and development costs are tracked by our COVID vaccine program and our lantibiotics program. Due to limited resources, while we continue our development efforts, we have focused on reducing our research and development expenses until we can raise additional capital.

Our current product development strategy contemplates continued research and development expenses in the future as we further the advancement of our product development programs for our vaccine product candidates. Continued research and development expenses are 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 the License Agreements as to the planning and timing of our research and development and therefore the timing of when expenditures may be incurred for various phases of agreed upon projects, actual expenditures can vary from period to period. Subject to available capital, overall research and development expenses could increase as a result of our vaccine product candidate. Our research and development projects are currently expected to be taken to the point where they can be licensed or partnered with larger pharmaceutical companies.

Recent Financing

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

General and Administrative Expenses

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

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

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

Other Income (Expense)

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

Income Taxes

At December 31, 2022, the Company has federal and state tax net operating loss carryforwards of $150,083,903. Federal and state tax net operating loss carryforwards generated prior to December 31, 2017 will expire through 2037 and are not subject to taxable income limitations. Federal tax net operating loss carryforwards generated subsequent to December 31, 2017, do not expire but are subject to taxable income limitation pursuant to the Tax Cuts and Jobs Act that was enacted on December 22, 2017. State of Pennsylvania tax net operating loss carryforwards will expire through 2036. The Company also has federal research and development tax credit carryforwards of $4,834,847. The federal tax credit carryforward will expire beginning in 2021 and continuing through 2042 unless previously utilized.

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

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

Grant revenue. Grant revenue was $7,466 for the three months ended September 30, 2023 compared to $86,047 for the three months ended September 30, 2022, a decrease of $78,581 or 91.3%. This decrease was attributable to awards received for a small business innovation research grant that expired in the three-month period ended September 30, 2023.

Research and Development. Research and development expenses were $769,353 for the three months ended September 30, 2023 compared to $2,777,068 for the three months ended September 30, 2022, a decrease of $2,007,718 or 72%.

	For the Three Months Ended September 30, 2023	For the Three Months Ended September 30, 2022
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	236,193	296,916
COVID Vaccine Development Expense		
Clinical Research	297,351	678,500
Non-clinical research and development activities	235,809	1,801,652
Total Research and development activities	**$ 769,353**	**$ 2,777,068**

This decrease was mainly driven by approximately $2 million of decreased costs associated with the development of our COVID vaccine product and primarily associated with costs for outside consultants. Additionally, there were decreases in research and development expenses for our lantibiotic product of approximately $60,723 in the three months ended September 30, 2023, which decreases were largely related to the closing of the Alachua, Florida facility.

General and Administrative. General and administrative expenses were $1,332,562 for the three months ended September 30, 2023 compared to $1,215,498 for three months ended September 30, 2022, an increase of approximately $117,064 or 10% This increase was primarily due to increased expenses related to:

- Accounting expense of $39,000,
- Loss on the sale of fixed assets of $22,443,
- Legal expenses of approximately $25,841,
- Options expense of approximately $409,724 and
- Rent and utility expenses of approximately $20,814

These expense increases were offset by decreases in:

- Consultant expense of approximately $64,329,
- Insurance expense of approximately $25,183,
- Public company related expenses of approximately $70,128 and
- Stock compensation expense of $404,396

Other Income (Expense). Other income, net was $81,561 for the three months ended September 30, 2023 compared to $36,406 for the three months ended September 30, 2022, resulting in an increase of $45,155 or 124%. The net change was primarily attributable to $50,000 received in the material transfer agreement with Lantern Bioworks in the three-month period ended September 2023.

Results of Operations for the Nine Months Ended September 2023 and 2022

Grant revenue. Grant revenue was $37,653 for the nine months ended September 30, 2023 compared to $131,521 for the nine months ended September 30, 2022, a decrease of $78,581 or 71.4%. This decrease was attributable to awards received for a small business innovation research grant that expired in July of 2023.

Research and Development. Research and development expenses were $4,448,623 for the nine months ended September 30, 2023 compared to $8,660,761 for the nine months ended September 30, 2022, a decrease of $4.2 million or 49.0%.

	For the Nine Months Ended September 30, 2023	For the Nine Months Ended September 30, 2022
Lantibiotics Expense		
Clinical Research	$ -	$ -
Non-clinical research and development activities	727,697	976,122
COVID Vaccine Development Expense		
Clinical Research	950,575	3,240,858
Non-clinical research and development activities	2,770,351	4,443,781
Total Research and development activities	**$ 4,448,623**	**$ 8,660,761**

This decrease was primarily due to approximately $3.9 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, benefits and options expense, and other overhead expenses of approximately; $52,000, $60,000, and $37,000 respectively. Additionally, there was approximately $21,000 in decreased research and development related expense for the lantibiotic product. These decreases were offset by an increase in rent expense of approximately $107,000 related to the termination of the lease for the Alachua, Florida facility. 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 $3,697,609 for the nine months ended September 30, 2023 compared to $3,592,361 for nine months ended September 30, 2022, an increase of approximately $105,000 or 3% This increase was primarily due to increased expenses related to:

- Accounting expense of approximately $138,000,
- Consultant expense of approximately $264,000
- Other overhead related expenses for rent, utilities, insurance, and employee related expenses of approximately $300,000
- Stock compensation expense of approximately $400,000

These expense increases were offset by decreases in:

- Board of Directors related expense and stock options expense of approximately $722,000,
- Public company related expense of approximately $220,000, and
- Other overhead related expenses of approximately $45,000

Other Income (Expense) Other income, net was $200,271 for the nine months ended September 30, 2023 compared to $70,952 for the nine months ended September 30, 2022, resulting in an increase of $129,319 or 182.3%. The net change was primarily attributable to an increase in interest income of $102,859, for the nine-month period ended September 30, 2023 compared to 2022. The increase in interest income was attributable to the increase in savings account interest rates. Increases in other income are also attributable to $50,000 received in the material transfer agreement with Lantern Bioworks in the three-month period ended September 2023.

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 nine months ended September 30, 2023 and 2022 our operating activities used cash of $6,188,335 and $12,795,647 respectively. The decrease primarily resulted from decreased net losses, adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of $6,411,985 and $12,675,299 at September 30, 2023 and December 31, 2022, respectively.

During the nine months ended September 30, 2023 and 2022, our investing activities provided cash of $63,715 and used cash of $112,081 respectively. The cash provided by investing activities for the nine months ended September 30, 2023 was primarily due to the sale of lab equipment from the closing of the Alachua facility in September.

During the nine months ended September 30, 2023 and 2022, our financing activities provided cash of $464,479 and used cash of $406,921 respectively. The cash provided by financing activities during the nine months ended September 30, 2023 was primarily due to proceeds from a private placement of common stock offset by the repayment of short-term notes payable.

The Company has made several changes to reduce cash used in operations until additional capital can be obtained. These changes include a reduction in staffing and overhead costs related to the leased facility in Alachua Florida, as well as reduced research and development activity. These changes have positively impacted the forecast of cash resources available for operations, which we believe will allow us to fund our operating plan through the first quarter of 2024.

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 24, 2023 we entered into an ATM with Ladenburg Thalmann & Co. Inc ("Ladenburg") to sell shares of our common stock (the "ATM Program"). 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 nine-month period ended September 30, 2023 we did not issue any shares of common stock under our ATM program.

Other Financings

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

In July of 2023, we entered into a short-term note payable for $611,109 bearing interest at a rate of 9.55% to finance the renewals of the directors' and officers' liability, employment practices liability, products liability, cyber liability, and other liability policies. Principal and interest payments on the note began in August of 2023 and continue through May of 2024 based on straight-line amortization over the 10-month period.

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 were made evenly based on a straight-line amortization over a 10-month period the final payment was due on May 24, 2023.

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

Our Outstanding Preferred Stock

During 2017, we issued shares of Series A and Series B Preferred Stock in financing transactions (the "Preferred Stock Financings"). In connection with the Preferred Stock Financings, we filed Certificate of Designations of Preferences, Rights and Limitations of Series A and Series B Preferred Stock with the Secretary of State of the State of Florida, effective May 10, 2017 and November 8, 2017, respectively. On August 26, 2022, holders of 4,000,000 shares of the Company's Series A Convertible Preferred Stock, and 2,550,000 shares of the Company's Series B Convertible Preferred Stock converted the Series A Convertible Preferred Stock and the Series B Convertible Preferred Stock into an aggregate of 15,167 shares of common stock. As of September 30, 2023, our outstanding Series A and Series B Preferred Stock and the amount of common stock that may be issued upon conversion are set forth below:

Preferred Stock Series	Outstanding Shares	Common Stock Equivalents
Series A Preferred	5,417,000	9,028
Series B Preferred	4,050,000	13,500

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

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

Future Capital Requirements

Our capital requirements for the remainder of 2023 and the first nine months of 2024 will depend on numerous factors, including our ability to successfully consummate the Odyssey asset purchase, 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. Additionally, pursuant to the Odyssey Asset Purchase Agreement, on or about October 4, 2023, we paid Odyssey $500,000 and we are obligated to pay Odyssey an additional $500,000 upon the earlier of (a) the closing of the Purchase Agreement, (b) within three (3) business days after the date that Odyssey has obtained its stockholders' approval approving the Odyssey Asset Purchase and (c) immediately upon the Company's wrongful termination of the Purchase Agreement in breach of the Purchase Agreement.

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 first quarter of 2024. As a result, we have implemented certain cost-saving initiatives, including reducing our efforts and staff focused on our lantibiotics program, which are expected to negatively impact the development of our lantibiotics program. See, "Risk Factors." We expect to manage the timing of our development expenditures and to continue to seek additional funding for our operations. Any 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, as well as the development of assets we hope to acquire from Odyssey, 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:

- our ability to successfully consummate the Odyssey asset purchase;
- conducting preclinical research for our NT-CoV2-1 vaccine 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 on Form 10-Q, filed with the SEC on May 13, 2022 (the "Q1 2022 10-Q"); and

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

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

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

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

Recently Issued Accounting Pronouncements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

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

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

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

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

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

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

The Company determined that the reporting effects of the above errors had a material impact to the Company's unaudited consolidated financial statements of the Company for the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q. As a result, the Company determined that the unaudited consolidated financial statements should be restated, and the Company should file an amendment to the Q1 2022 10-Q, Q2 2022 10-Q, and Q3 2022 10-Q with the SEC. All such amendments were filed with the SEC on April 14, 2023. When referencing prior period comparisons for the three and nine-month periods ended September 30, 2022 in this Form 10-Q for the three and nine-month periods ended September 30, 2023 the financial information reflects the restated financials as reported in the Q3 2022 10-Q.

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, currently staff have returned to working in the office at least 50% of the time. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting. We will continue to monitor and assess the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Limitations on the Effectiveness of Controls

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

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

In addition to the other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection "Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 which could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection "Risk Factors" to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed on April 17, 2023. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption "Risk Factors" in our Annual Report on Form 10-K.

Risks Related to Our Business

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

We have incurred significant net losses and negative cash flow in each year since our inception, including net losses of approximately $7.9 million and $12.1 million for the nine months ended September 30, 2023 and 2022, respectively, and approximately $14.3 million for the year ended December 31, 2022. As of September 30, 2023, our accumulated deficit was approximately $193.5 million. We have devoted a significant amount of our financial resources to research and development, including our nonclinical development activities and clinical trials. We expect that the costs associated with our plans to begin preclinical research, contract manufacturing and file an IND for our NT-CoV2-1 vaccine product candidate will continue and, to have successful results, likely will require an increase in the level of our overall expenses going forward. As a result, we expect to continue to incur substantial net losses and negative cash flow for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations. As a result of our limited resources, we have undertaken cost-saving initiatives, including reducing our efforts and staff focused on our lantibiotics program. Our actual costs may ultimately vary from our current expectation, which could materially impact our use of capital and our forecast of the period of time through which our financial resources will be adequate to support our operations. Because of the numerous risks and uncertainties associated with product development and commercialization, we are unable to accurately predict the timing or amount of substantial expenses or when, or if, we will be able to generate the revenue necessary to achieve or maintain profitability. Due to of our accumulated losses and substantial doubt that we can continue as a going concern beyond March 2024, the Company is evaluating various opportunities for its Lantibiotics Program and its N-CoV2-1 vaccine product candidate, as well as alternative assets that could be acquired or developed. These opportunities could include a wide range of options including, among other things, a potential sale, spin-off, fund raising, combination or other strategic transaction, which may also include the winding down of research and development activities. The result of this process may result in the liquidation of assets for significantly less than amounts that have been invested in them, the write-off of prior expenses incurred in connection with the development of such assets and may have a material adverse effect on our results of operations and liquidity. Notwithstanding the above, the Company will seek to maximize the value of such assets to the extent possible. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate or government collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We believe our existing cash will allow us to fund our operating plan only through the first quarter of 2024.

We may not be able to successfully consummate the Odyssey Asset Purchase.

The closing of the Odyssey Asset Purchase is subject to various closing conditions, including without limitation the following: (1) Odyssey shall have obtained all required consents to the Odyssey Asset Purchase; (2) Odyssey shall have obtained its shareholders' approval to the Odyssey Asset Purchase; (3) the Company's shareholders shall have approved (a) the increase in the Company's authorized Common Stock from 4,166,666 to 350,000,000 and (b) the conversion of the Series F Preferred Stock into Common Stock; (4) no material adverse change shall have occurred to the Purchased Assets; (5) the Company must have at least $5,000,000 in cash at Closing; and (6) the Company must have completed its due diligence of the Purchased Assets to its satisfaction. There can be no assurances that such conditions will be satisfied. The Company previously has had difficulty in obtaining a quorum at its shareholders meetings. If the Company does not establish a quorum at its next shareholders meeting or does not receive sufficient votes in favor of the increase in its authorized Common Stock or to approve the conversion of the Series F Preferred Stock into Common Stock, the Company may be unable to consummate the Odyssey Asset Purchase. In such event, either party to the Purchase Agreement may terminate the agreement and the Company may and likely will be unable to obtain the return of the cash payment made to Odyssey. Failure to consummate the Odyssey Asset Purchase may also make it more difficult for the Company to raise additional capital. As previously disclosed, we need to raise additional capital to complete the development and commercialization of our product candidates and operate our business.

We may have difficulty raising additional capital, which could deprive us of the resources necessary to implement our business plan, which would adversely affect our business, results of operation and financial condition.

Whether or not we successfully consummate the Odyssey Asset Purchase, we need to raise additional capital to fund the development and commercialization of our product candidates and to operate our business. The need to raise additional capital is expected to increase if we successfully consummate the Odyssey Asset Purchase. Part of the purchase price we are paying Odyssey is $1,000,000 in cash. Additionally, if we consummate the Odyssey Asset Purchase, we expect our operating expenses to increase, both due to additional employment costs and operating costs required to pursue the development of the assets we hope to purchase from Odyssey. In order to support the initiatives envisioned in our business plan, we will need to raise additional funds through the sale of assets, public or private debt or equity financing, collaborative relationships or other arrangements. If our operations expand faster or at a higher rate than currently anticipated, we may require additional capital sooner than we expect. We are unable to provide any assurance or guarantee that additional capital will be available when needed by our company or that such capital will be available under terms acceptable to our company or on a timely basis.

Our ability to raise additional financing depends on many factors beyond our control, including the state of capital markets, the market price of our common stock and the development or prospects for development of competitive products by others. If additional funds are raised through the issuance of equity, convertible debt or similar securities of our company, the percentage of ownership of our company by our company's stockholders will be reduced, our company's stockholders may experience additional dilution upon conversion, and such securities may have rights or preferences senior to those of our common stock. The preferential rights granted to the providers of such additional financing may include preferential rights to payments of dividends, super voting rights, a liquidation preference, protective provisions preventing certain corporate actions without the consent of the fund providers, or a combination thereof. We are unable to provide any assurance that additional financing will be available on terms favorable to us or at all.

If adequate funds are not available or are not available on acceptable terms, our ability to take advantage of the potential of assets acquired from Odyssey will be limited significantly. With limited capital, we expect to continue to scale back or delay implementation of research and development of our lantibiotics and Covid programs and may choose instead to focus the limited capital on the concussion asset purchased from Odyssey. Thus, the unavailability of capital could substantially harm our business, results of operations and financial condition.

Our success with regard to the Purchased Assets depends on the viability of our business strategy with regard to those assets, which is unproven and may be unfeasible.

Our revenue and income potential with regard to the Odyssey Purchased Assets, in particular the concussion asset, are unproven, and we continue to develop our strategy for such assets. Our anticipated business model is based on a variety of assumptions based on a growing trend in the healthcare systems in the United States and many other countries. These assumptions may not reflect the business and market conditions we actually face. As a result, our operating results could differ materially from those projected under our business model, and our business model may prove to be unprofitable.

The product candidate ONP-002 (the concussion asset) being developed by Odyssey, which development we will continue if we successfully consummate the Odyssey Asset Purchase, is in its early stages and will require extensive testing and clinical trials before it is commercialized. There is no guarantee that ONP-002 will be approved for commercial use.

The product candidate ONP-001 (the potential treatment for Niemann Pick Disease Type C) we are acquiring from Odyssey, is in its early stages and will require extensive testing and clinical trials before it is commercialized. There is no guarantee that ONP-001 will be approved for commercial use. Odyssey currently owns only 50% of the intellectual property related thereto. The other 50% is owned by a third party. The joint venture with that third party has not been finalized.

If we fail to obtain marketing authorization for these product candidates, our business, financial condition, and results of operations will be materially adversely affected.

There are substantial inherent risks in attempting to commercialize newly developed products, and, as a result, we may not be able to successfully develop the new products acquired from Odyssey.

If we successfully consummate the Odyssey Asset Purchase, we hope to conduct research and development of the purchased technologies. However, commercial feasibility and acceptance of such product candidates are unknown. Scientific research and development require significant amounts of capital and takes an extremely long time to reach commercial viability, if at all. During the research and development process, we may experience technological barriers that we may be unable to overcome. Because of these uncertainties, it is possible that some of our future product candidates will never be successfully developed. If we are unable to successfully develop new products, we may be unable to generate new revenue sources or build a sustainable or profitable business.

Additionally, if we successfully consummate the Odyssey Asset Purchase, since we operate with limited resources and staff, our attention and resources will be diverted away from our existing lantibiotic and Covid programs, possibly resulting in further delays in the development and commercialization of such programs.

We will need to achieve commercial acceptance of our products, if cleared or approved, to generate revenues and achieve profitability.

If we successfully consummate the Odyssey Asset Purchase, superior products may be introduced that compete with the Purchased Assets, which would diminish or extinguish the uses for the products candidates acquired from Odyssey, if cleared or approved. We cannot predict when significant commercial market acceptance for such products, if cleared or approved, will develop, if at all, and we cannot reliably estimate the projected size of any such potential market. If markets fail to accept such products, then we may not be able to generate revenue from them. Our revenue growth and achievement of profitability will depend substantially on our ability to introduce new products that are accepted by customers. Our competitors in the industry are predominantly large companies with longer operating histories, with significantly easier access to capital and other resources and an established product pipeline than us. There can be no assurance that we will be able to establish ourselves in our targeted markets, or, if established, that we will be able to maintain our market position, if any. Our commercial opportunity may be reduced if our competitors develop new or improved products that are more convenient, more effective or less expensive than our product candidates are. Competitors also may obtain FDA or other regulatory marketing authorization for their products more rapidly or earlier than we may obtain marketing authorization for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. If we are unable to cost-effectively achieve acceptance of our products by customers, or if our products do not achieve wide market acceptance, then our business will be materially and adversely affected.

The products candidates we hope to acquire from Odyssey are still in development, and Odyssey has not obtained authorization from any regulatory agency to commercially distribute such products in any country and we may never obtain such authorizations.

We currently have no products authorized for commercial distribution in either the United States, Europe or any other country. Similarly, the products candidates we hope to acquire from Odyssey are still in development. Like the product candidates we are developing, the Purchased Assets require regulatory clearance or approvals. We cannot begin marketing and selling product candidates until we obtain applicable authorizations from the applicable regulatory agencies. The process of obtaining regulatory authorization is expensive and time-consuming and can vary substantially based upon, among other things, the type, complexity and novelty of a product candidate. Changes in regulatory policy, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application may cause delays in the authorization of a product candidate or rejection of a regulatory application altogether.

The FDA has substantial discretion in the review process and may refuse to accept our application or may decide that data are insufficient to grant the request and require additional pre-clinical, clinical, or other studies. In addition, varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit, or prevent marketing authorization from the FDA or other regulatory authorities. Any marketing authorization from the FDA we ultimately obtain may be limited or subject to restrictions or post-market commitments that render the product candidate not commercially viable. If our attempts to obtain marketing authorization are unsuccessful, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be materially adversely affected.

We are, and will continue to be, dependent in significant part on outside scientists and third-party research institutions for our research and development in order to be able to commercialize our product candidates.

We currently have a limited number of employees and resources available to perform the research and development necessary to commercialize our product candidates and potential future product candidates. We therefore rely, and will continue to rely, on third-party research institutions, collaborators and consultants for this capability. This will remain the case if we successfully consummate the Odyssey Asset Purchase. As previously announced, we recently exercised our option under our lease with Hawley-Wiggins, LLC, a Florida Limited Liability Company (the "Landlord"), for the building located in Progress Park and known as 13700 Progress Boulevard, Alachua, Florida 32615 (the "Lease") to terminate the Lease by paying nine (9) months of advance rent, plus prorated rent for the month of September, plus applicable sales tax. In addition to the termination of the Lease, the Company eliminated two staff positions and Dr. Martin Handfield transitioned from an employee of the Company to a consultant. Dr. Handfield continues to be available to provide support services on an hourly basis through a consulting agreement. Dr. Handfield's employment agreement was terminated in accordance with its terms. The Alachua lease contained the laboratory where some of the research and development for the lantibiotic program was undertaken. The Company expects to continue its research and development of lantibiotics to fight infectious diseases as capital resources become available and would look to use laboratory facilities of third parties as considered necessary. While the Company continues to seek additional funding, it is taking steps to reduce the use of its cash resources, which include the determination to terminate the Lease.

We are heavily dependent upon the ability and expertise of our management team and a very limited number of employees and the loss of such individuals could have a material adverse effect on our business, operating results or financial condition.

We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management. While employment agreements are customarily used as a primary method of retaining the services of key employees, these agreements cannot assure the continued services of such employees. Any loss of the services of such individuals could have a material adverse effect on our business, operating results or financial condition.

We believe that our future success with regard to the assets we hope to purchase from Odyssey will depend significantly on the skills and efforts of Joseph Michael Redmond, President and CEO of Odyssey, and possibly other key personnel. We expect that Mr. Redmond will join the Oragenics' management team upon the closing of the Odyssey Asset Purchase. The loss of the services of any of these individuals could harm our ability to successfully pursue the development of the Purchased Assets. If any of our executive officers or key employees left or was seriously injured and unable to work and we were unable to find a qualified replacement and/or to obtain adequate compensation for such loss, we may be unable to manage our business, which could harm our operating results and financial condition.

If we successfully consummate the Odyssey Asset Purchase, we anticipate growth in our business and increased costs, and any inability to manage such growth could harm our business.

Our success will depend, in part, on our ability to effectively manage our growth and expansion. Any growth in, or expansion of, our business is likely to continue to place a significant strain on our management and administrative resources, infrastructure and systems. In order to succeed, we will need to continue to implement management information systems and improve our operating, administrative, financial and accounting systems and controls. We will also need to train new employees and maintain close coordination among our executive, accounting, finance and operations organizations. These processes are time-consuming and expensive, will increase management responsibilities and will divert management attention. Our inability or failure to manage our growth and expansion effectively could substantially harm our business and adversely affect our operating results and financial condition.

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

None, other than those previously disclosed on the Company's Current Reports on Form 8-K.

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	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K		3.1	1/23/23	
3.7	Certificate of Designation	8-K		3.1	8/7/23	
3.8	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.9	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.10	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.11	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	NRC Technology License Amendment 5 (dated April 3, 2023)*	10-Q	10.7	5/12/23	
10.6	Three-Way Collaborative Research Agreement*	10-Q		8/11/23	
10.7	Form of Securities Purchase Agreement	8-K	10.1	8/7/23	
10.8	Asset Purchase Agreement	8-K	2.1	10/5/23	
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.				X
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14 and Rule 15d-14(a), promulgated under the Securities and Exchange Act of 1934, as amended.				X
32.1	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Principal Executive Officer).				X
32.2	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Financial Officer).				X
101.INS	Inline XBRL Instance Document				
101.SCH	Inline XBRL Taxonomy Extension Schema				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase				X
104	Cover Page Interactive Data File (embedded within the Inline XBRL document				

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

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 9th day of November 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 31.1

CERTIFICATION

I, Kimberly Murphy, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date : November 9, 2023

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

Exhibit 31.2

CERTIFICATION

I, Janet Huffman, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 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 September 30, 2023 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Kimberly Murphy, hereby certify, to the best of my knowledge, that:

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

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

/s/ Kimberly Murphy

Name: Kimberly Murphy
President and Principal Executive Officer

Date: November 9, 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 September 30, 2023 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, Janet Huffman, hereby certify, to the best of my knowledge, that:

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

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

/s/ Janet Huffman

Name: Janet Huffman
Principal Financial Officer

Date: November 9, 2023