

**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, 2024.

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
(State or other jurisdiction of
incorporation or organization)

59-3410522
(IRS Employer
Identification No.)

1990 Main Street Suite 750
Sarasota, Florida 34236
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 13, 2024, there were 12,212,680 shares of Common Stock, \$0.001 par value, outstanding.

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PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 3,144,049	\$ 3,483,501
Prepaid expenses and other current assets	969,294	382,273
Total current assets	4,113,343	3,865,774
Prepaid research and development expense	1,090,750	1,090,750
Operating lease right-of-use assets	-	9,811
Total assets	<u>\$ 5,204,093</u>	<u>\$ 4,966,335</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,607,114	\$ 1,475,667
Short-term notes payable	519,392	312,703
Operating lease liabilities - Current	-	9,811
Total liabilities	2,126,506	1,798,181
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, 7,488,692 and 7,488,692 Series F shares outstanding at September 30, 2024 and December 31, 2023, respectively	1,592,723	1,592,723
Common stock, \$0.001 par value; 350,000,000 shares authorized and 9,387,547 and 3,080,693 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	9,388	3,081
Additional paid-in capital	214,912,523	207,790,604
Accumulated Deficit	(213,437,047)	(206,218,254)
Total shareholders' equity	3,077,587	3,168,154
Total liabilities and shareholders' equity	<u>\$ 5,204,093</u>	<u>\$ 4,966,335</u>

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		For the Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
	(Unaudited)		(Unaudited)	
Grant revenue	\$ -	\$ 7,466	\$ -	\$ 37,653
Operating expenses:				
Research and development	879,041	769,350	2,449,234	4,448,623
General and administrative	1,558,239	1,332,562	4,754,149	3,697,609
Total operating expenses	<u>2,437,280</u>	<u>2,101,912</u>	<u>7,203,383</u>	<u>8,146,232</u>
Loss from operations	(2,437,280)	(2,094,446)	(7,203,383)	(8,108,579)
Other income (expense):				
Interest income	9,466	50,613	35,106	171,768
Interest expense	(9,971)	(14,170)	(18,859)	(18,360)
Other income	-	45,118	-	46,863
Foreign currency exchange net	(25,085)	-	(31,659)	-
Total other income (expense), net	<u>(25,590)</u>	<u>81,561</u>	<u>(15,412)</u>	<u>200,271</u>
Loss before income taxes	<u>(2,462,870)</u>	<u>(2,012,885)</u>	<u>(7,218,795)</u>	<u>(7,908,308)</u>
Income tax benefit	-	-	-	-
Net loss	<u>\$ (2,462,870)</u>	<u>\$ (2,012,885)</u>	<u>\$ (7,218,795)</u>	<u>\$ (7,908,308)</u>
Basic and diluted net loss per share	<u>\$ (0.38)</u>	<u>\$ (0.85)</u>	<u>\$ (1.49)</u>	<u>\$ (3.70)</u>
Shares used to compute basic and diluted net loss per share	<u>6,528,064</u>	<u>2,356,065</u>	<u>4,857,182</u>	<u>2,136,340</u>

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

Orogenics, Inc.
Condensed Consolidated Statements of Changes in Shareholders' Equity

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2023	<u>3,080,693</u>	<u>\$ 3,081</u>	<u>16,955,197</u>	<u>\$ 1,592,723</u>	<u>\$ 207,790,604</u>	<u>\$ (206,218,254)</u>	<u>\$ 3,168,154</u>
Compensation expense relating to option issuances	—	—	—	—	69,344	—	69,344
Sale of Common Stock	1,400,000	1,400	—	—	1,837,201	—	1,838,601
Net loss	—	—	—	—	—	(2,450,833)	(2,450,833)
Balances at March 31, 2024	<u>4,480,693</u>	<u>4,481</u>	<u>16,955,197</u>	<u>1,592,723</u>	<u>209,697,149</u>	<u>(208,669,087)</u>	<u>2,625,266</u>
Compensation expense relating to option issuances	—	—	—	—	58,220	—	58,220
Sale of Common Stock	1,100,000	1,100	—	—	946,900	—	948,000
Net loss	—	—	—	—	—	(2,305,090)	(2,305,090)
Balances at June 30, 2024	<u>5,580,693</u>	<u>5,581</u>	<u>16,955,197</u>	<u>1,592,723</u>	<u>210,702,269</u>	<u>(210,974,177)</u>	<u>1,326,396</u>
Compensation expense relating to option issuances	—	—	—	—	330,802	—	330,802
Sale of Common Stock	3,806,854	3,807	—	—	3,879,452	—	3,883,259
Net loss	—	—	—	—	—	(2,462,870)	(2,462,870)
Balances at September 30, 2024	<u>9,387,547</u>	<u>\$ 9,388</u>	<u>16,955,197</u>	<u>\$ 1,592,723</u>	<u>\$ 214,912,523</u>	<u>\$ (213,437,047)</u>	<u>\$ 3,077,587</u>

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2022	<u>2,024,657</u>	<u>\$ 2,025</u>	<u>9,467,000</u>	<u>\$ 1,592,723</u>	<u>\$ 196,977,071</u>	<u>\$ (185,562,517)</u>	<u>\$ 13,009,302</u>
Compensation expense relating to option issuances	—	—	—	—	79,966	—	79,966
Net loss	—	—	—	—	—	(2,844,837)	(2,844,837)
Balances at March 31, 2023	<u>2,024,657</u>	<u>2,025</u>	<u>9,467,000</u>	<u>1,592,723</u>	<u>197,057,037</u>	<u>(188,407,354)</u>	<u>10,244,431</u>
Compensation expense relating to option issuances	—	—	—	—	63,628	—	63,628
Net loss	—	—	—	—	—	(3,050,586)	(3,050,586)
Balances at June 30, 2023	<u>2,024,657</u>	<u>2,025</u>	<u>9,467,000</u>	<u>1,592,723</u>	<u>\$ 197,120,665</u>	<u>(191,457,940)</u>	<u>7,257,473</u>
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	<u>2,569,385</u>	<u>\$ 2,549</u>	<u>9,467,000</u>	<u>\$ 1,592,723</u>	<u>\$ 198,372,874</u>	<u>\$ (193,470,825)</u>	<u>\$ 6,497,321</u>

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	(7,218,795)	(7,908,308)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	-	27,391
Gain on sale of property and equipment	-	(22,443)
Stock-based compensation expense	458,366	546,519
Changes in operating assets and liabilities:		
Other receivables	-	(35,104)
Prepaid expenses and other current assets	49,951	1,443,563
Operating lease right of use assets	9,811	323,103
Deposits	-	9,340
Accounts payable and accrued expenses	131,449	(572,396)
Change in operating lease liabilities	(9,811)	-
Net cash used in operating activities	(6,579,029)	(6,188,335)
Cash flows from investing activities:		
Proceeds from sale of property and equipment	-	63,715
Net cash provided by (used in) investing activities	-	63,715
Cash flows from financing activities:		
Payments on short-term notes payable	(430,283)	(385,329)
Net proceeds from issuance of common stock	6,669,860	849,808
Net cash provided by (used in) financing activities	6,239,577	464,479
Net decrease in cash and cash equivalents	(339,452)	(5,660,141)
Cash and cash equivalents at beginning of period	3,483,501	11,426,785
Cash and cash equivalents at end of period	\$ 3,144,049	\$ 5,766,644
<i>Supplemental disclosure of cash flow information:</i>		
Interest paid	\$ 18,859	\$ 3,347
Non-cash investing and financing activities:		
Borrowings under short term notes payable for prepaid expense	\$ 636,972	\$ 611,109

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”) was incorporated in November 1996. We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications and therapies.

Commencing in December of 2023, we are focused on the development of medical products that treat brain related illnesses and diseases and our lead product candidate and focus is on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury (“mTBI” or “Concussion”).

Prior to the purchase of our lead asset ONP-002, starting in May 2020 and through December 31, 2023 our lead asset was a nasal delivery vaccine candidate to provide long-lasting immunity from SARS-CoV-2, which causes COVID-19.

Currently research and development activities related to the nasal vaccine platform and our lantibiotic program are inactive, we will evaluate alternative opportunities for these programs 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 condensed consolidated financial statements as of September 30, 2024 and December 31, 2023 and for the three and nine months ended September 30, 2024 and 2023, have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim condensed 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 condensed consolidated financial statements. In the opinion of management, the accompanying condensed 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, 2024 are not necessarily indicative of the results of operations that may be expected for the year ended December 31, 2024, or any future period.

These condensed consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto for the year ended December 31, 2023, which are included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 29, 2024.

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 \$7,218,795 and used cash of \$6,579,029 in its operating activities during the nine months ended September 30, 2024. As of September 30, 2024, the Company had an accumulated deficit of \$213,437,047.

The Company expects to incur substantial expenditures to further develop its technologies. The Company believes its working capital at September 30, 2024 will be sufficient to meet the business objectives as presently structured only through the fourth 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 corporate office located in Tampa, Florida.

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

The Company intends to seek additional funding through sublicensing arrangements, joint venturing or partnering, sales of rights to technology, government grants and public or private financings. The Company’s future success depends on its ability to raise capital and ultimately generate revenue and attain profitability. The Company cannot be certain that additional capital, whether through selling additional debt or equity securities or obtaining a line of credit or other loan, will be available to it or, if available, will be on terms acceptable to the Company. In the nine-month period ended September 30, 2024 the Company secured funding through the sale of approximately 5.6 million shares of its common stock and approximately 5 million prefunded warrants to purchase shares of common stock in three public offerings; the gross proceeds from the offerings, in the aggregate, were approximately \$7.7 million before underwriting discounts, commissions, and other expenses payable by 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 condensed consolidated financial statements include the accounts of Orogenics, Inc. and our wholly owned subsidiaries Noachis Terra, Inc. ("NTI") and Orogenics Australia Pty Ltd. 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, 2024, that have had, or are expected to have, a material impact on our condensed consolidated financial statements.

Use of Estimates

The preparation of condensed 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 condensed 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 condensed 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.

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. Net loss per share is computed using the weighted average number of shares of common stock outstanding.

4. Prepaid Expense, Deposits, and Other Current Assets

Prepaid expenses, deposits, and other current assets consist of the following at September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Prepaid research and development expense, current	\$ 386,035	\$ —
Prepaid insurance	531,701	334,940
Other prepaid expense, current	51,558	47,333
Prepaid research and development expense, long-term	1,090,750	1,090,750
Total prepaid expense, deposits, and other current assets	\$ 2,060,044	\$ 1,473,023

5. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consist of the following as of September 30, 2024, and December 31, 2023:

	September 30, 2024	December 31, 2023
Accounts payable trade	\$ 1,513,287	\$ 1,244,947
Accrued expenses	65,657	222,739
Accrued Vacation	28,170	7,981
Total accounts payable and accrued expenses	\$ 1,607,114	\$ 1,475,667

6. Short-Term Notes Payable

The Company had the following short-term notes payable as of September 30, 2024 and December 31, 2023:

	September 30, 2024	December 31, 2023
Insurance premium financing of \$636,972 and \$611,109 due in monthly installments of \$67,277 and \$54,366 including principal and interest at 9.55% through May 24, 2025 and 2024 respectively.	\$ 519,392	\$ 312,703
	<u>\$ 519,392</u>	<u>\$ 312,703</u>

The Company's policy renewals were completed in July of 2024.

7. Shareholders' Equity

Common Stock

Other Share Issuances

Pursuant to the Company's effective registration statement on Form S-3 (File No. 333-269225) and a related prospectus and prospectus supplement, in each case filed with the Securities and Exchange Commission; on March 1, 2024, through an underwriting agreement (the "Underwriting Agreement") with ThinkEquity, LLC as representative (the "Representative") of the underwriters (collectively, the "Underwriters"), the Company sold 1,400,000 shares of common stock at a price of \$1.50 per share to the public. According to the terms of the Underwriting Agreement, the Underwriters agreed to purchase the common shares at a price of \$1.395 per share. The Company also granted the Underwriters an option exercisable for 45 days from the date of the Underwriting Agreement to purchase up to an additional 210,000 shares of common stock solely for the purpose of covering over-allotments (the "Over-allotment Options"). No Over-allotment Options were exercised. The Company also agreed to issue warrants to the designees of the Representative exercisable one hundred eighty (180) days after February 27, 2024 and expiring on February 27, 2029, to purchase up to 5% of the shares sold through the Underwriting Agreement at an exercise price of \$1.875 per share. The gross proceeds from the sale of the shares were \$2.1 million before underwriting discounts and commissions and other expenses payable by the Company were deducted.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, conditions to closing, indemnification obligations of the Company and the Underwriters, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties and termination provisions.

On June 25, 2024 the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Dawson James Securities Inc. ("Dawson James" or the "Placement Agent") pursuant to which the Company engaged Dawson James as the placement agent for a registered public offering (the "Offering") of an aggregate of 1,100,000 shares of the Company's common stock, par value \$0.001 ("Common Stock"). The Offering was undertaken pursuant to the Company's effective registration statement on Form S-3 (File No. 333-269225) and a related prospectus and prospectus supplement filed with the Securities and Exchange Commission. The offering price per share of Common Stock was \$1.00. The Company agreed to pay the Placement Agent a placement agent fee in cash equal to 7.00% of the gross proceeds from the Offering, and to reimburse for certain out of pocket expenses, including legal fees not to exceed \$75,000. In addition, the Company agreed to issue to the Placement Agent warrants to purchase up to five percent 5% of the aggregate number of securities sold in the Offering ("Dawson James Warrants") with an exercise price of 125% of the offering price of the Common Stock in the Offering and exercisable for five years from the date of the closing of the Offering and are initially exercisable six months from the closing of the Offering.

The Offering resulted in gross proceeds to the Company of \$1.1 million before underwriting discounts and commissions and other expenses payable by the Company were deducted.

The Placement Agency Agreement contains customary representations, warranties and agreements, conditions to closing, indemnification obligations of the Company, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties, and termination provisions.

On September 4, 2024, the Company entered into a second placement agency agreement (the "Second Placement Agency Agreement") with Dawson James Securities Inc. ("Dawson James" or the "Placement Agent") pursuant to which the Company engaged Dawson James as the placement agent for a registered public offering by the Company (the "Offering") of an aggregate of (i) 8,106,584 shares of its common stock, par value \$0.001 per share ("Common Stock"), or pre-funded warrants to purchase shares of Common Stock ("Pre-Funded Warrants") in lieu thereof (the "Offering"). In connection with the Offering, the Company entered into a securities purchase agreement (the "Purchase Agreement") with an institutional investor to purchase Common Stock and Pre-Funded Warrants. The Purchase Agreement contains customary representations, warranties and agreements of the Company and the purchaser and customary indemnification rights and obligations of the parties.

The Offering Price was \$0.55 per share of Common Stock. The Pre-Funded Warrants were priced at an offering price of \$0.549 per Pre-Funded Warrant, which is equal to the offering price per share of Common Stock less the \$0.001 per share exercise price of each such Pre-Funded Warrant. The Pre-Funded Warrants are immediately exercisable and terminate when exercised in full.

The Offering closed on September 5, 2024. Upon the closing of the Offering, the Company issued and sold 3,078,378 shares of Common Stock and Pre-Funded Warrants to purchase 5,028,206 shares of Common Stock.

Immediately after the Offering, the Company had 8,659,071 shares of Common Stock issued and outstanding and 5,028,206 Pre-Funded Warrants outstanding to acquire 5,028,206 shares of common stock. As of November 13, 2024 a total of 3,888,501 Pre-Funded Warrants were exercised for the same number of common shares and 1,139,705 Pre-Funded Warrants remain unexercised.

The Placement Agent agreed to use its reasonable best efforts to arrange for the sale of the Common Stock and Pre-Funded Warrants. The Company agreed to pay the Placement Agent a placement agent fee in cash equal to 7.00% of the gross proceeds from the sale of the Common Stock and Pre-Funded Warrants in this Offering. The Company also agreed to reimburse the Placement Agent for all reasonable travel and other out-of-pocket expenses, including the reasonable fees of legal counsel, not to exceed \$125,000. In addition, the Company agreed to issue to the Placement Agent warrants to purchase up to five percent 5% of the aggregate number of securities sold in the Offering (the “Placement Agent Warrants”) with an exercise price 125% of the offering price of the Common Stock in the Offering and exercisable commencing six months from the closing of the Offering and for five years thereafter.

The Offering resulted in gross proceeds to the Company of approximately \$4.45 million before deducting placement agent fees and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds of approximately \$3.79 million from the offering to fund the continued development of its ONP-002 product candidate and for general corporate purposes and working capital.

The Placement Agency Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company, including for liabilities under the Securities Act of 1933, as amended, other obligations of the parties, and termination provisions.

The Offering was made pursuant to a registration statement on Form S-1 (File No. 333-281618), which was declared effective by the Securities and Exchange Commission on September 3, 2024.

The Company also entered into a warrant agency agreement with its transfer agent, Continental Stock Transfer & Trust Company, who will act as warrant agent for the Company, setting forth the terms and conditions of the Pre-Funded Warrants sold in the Offering (the “Warrant Agency Agreement”).

8. At The Market

On October 11, 2024, the Company entered into an At-the-Market Sales Agreement (the “ATM Agreement”) with Dawson James Securities Inc. (“Dawson James” or the “Sales Agent”) pursuant to which the Company may issue and sell, from time to time, shares of its common stock (the “Shares”), depending on market demand, with the Sales Agent acting as the sales agent or principal (the “Offering”). Sales of the Shares may be made by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the “Securities Act”), including, without limitation, sales made directly on or through the NYSE American. The Agent will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf, consistent with the Agent’s normal trading and sales practices, under the terms and subject to the conditions set forth in the ATM Agreement. The Company has no obligation to sell any of the Shares. The Company may instruct the Agent not to sell the Shares if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the ATM Agreement.

The Company will pay the Agent a commission of up to 3.0% of the gross proceeds from the sale of Shares by the Agent under the ATM Agreement. The Company has also agreed to reimburse the Agent for the fees and disbursements of its counsel, payable upon execution of the Sales Agreement, in an amount not to exceed \$30,000 in addition to certain ongoing disbursements of its legal counsel up to \$2,500 per calendar quarter. In addition, the Company has agreed to provide customary indemnification rights to the Sales Agent.

Any sales of Shares under the ATM Agreement will be made pursuant to the Company’s Registration Statement on Form S-3 (File No. 333-269225), including the related prospectus, filed with the Securities and Exchange Commission (the “SEC”) on January 13, 2023, and declared effective on January 25, 2023, as supplemented by the prospectus supplement dated October 11, 2024, and any applicable additional prospectus supplements related to the Offering that form a part of the Registration Statement.

The aggregate market value of Shares eligible for sale in the Offering and under the ATM Agreement will be subject to the limitations of General Instruction I.B.6 of Form S-3, to the extent required under such instruction. The prospectus supplement filed with the SEC on October 11, 2024, is offering Shares having an aggregate offering price of \$10,000,000. The Company will be required to file another prospectus supplement in the event it determines to offer more than \$10,000,000 of Shares in accordance with the terms of the Sales Agreement, to the extent then permitted under General Instruction I.B.6 of Form S-3.

The Company intends to use the net proceeds from the offering to fund the continued development of its ONP-002 product candidate and for general corporate purposes and working capital. The precise amount and timing of the application of these proceeds will depend upon a number of factors, such as the timing and progress of our research and development efforts, our funding requirements and the availability and costs of other funds. As of November 13, 2024 there have been no shares sold under the ATM Agreement.

Previously, on August 8, 2024, the Company entered into an At-The-Market Issuance Sales Agreement (the “Sales Agreement”) with Ascendant Capital Markets, LLC, as sales agent (the “Agent”), pursuant to which the Company may offer and sell through or to the Agent (the “ATM”) up to \$10.0 million in shares of its common stock at-the-market. On October 9, 2024, the Company terminated the Sales Agreement with Ascendant Capital. There were no shares sold under the Sales Agreement with Ascendant Capital in the nine months ended September 30, 2024.

9. Warrants

The Company's outstanding and exercisable warrants as of September 30, 2024 are presented below:

	Number of Warrants	Weighted Average Exercise Price
Warrants outstanding at December 31, 2023	260,995	\$ 82.55
Issued	530,329	0.90
Expired	(43,862)	89.60
Warrants outstanding at September 30, 2024	<u>747,462</u>	<u>22.98</u>

Warrants Outstanding	Exercise Price	Expiration Date
10,888	\$ 186.00	11/8/2024
153,334	75.00	5/1/2025
52,911	60.00	7/17/2025
70,000	1.88	2/27/2029
55,000 ⁽¹⁾	1.25	6/29/2029
405,329 ⁽²⁾	0.69	9/4/2029
1,139,705 ⁽³⁾	0.001	
<u>1,887,167</u>		

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

(1)– Dawson James Placement Agent warrants are not exercisable until December 23, 2024.

(2)– Dawson James Placement Agent warrants are not exercisable until March 4, 2025.

(3)– Pre-Funded Warrants from September 5, 2024 financing not yet converted as of November 13, 2024.

10. Stock Compensation Plan

On September 29, 2023, the Board of Directors approved an amendment to the 2021 Equity Incentive Plan (the "Incentive Plan") to increase the authorized shares available under the Incentive Plan by 1,000,000. The amendment was approved by the Shareholders on December 14, 2023.

The Incentive Plan, as amended, provides aggregate number of shares of Common Stock that may be issued under the 2021 Plan will not exceed the sum of (i) 1,166,167 new shares, plus (ii) any shares remaining available for the grant of new awards under the 2012 Plan as of immediately prior to the effective date of the 2021 Equity Incentive Plan; plus, (iii) certain shares subject to outstanding awards granted under the 2012 Plan that may become available for issuance under the 2021 Equity Incentive Plan, as such shares become available from time to time.

Options are granted at the fair market value of the Company's stock on the date of the 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.

A summary of stock option activity for the nine months ended September 30, 2024 is as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (In Years)	Aggregate Intrinsic Value ⁽¹⁾
Outstanding at December 31, 2023	244,733	\$ 20.17	8.73	\$ 74,559
Granted	799,583	0.48	—	\$ —
Expired	(17,146)	28.44	—	\$ —
Forfeited	(4,667)	11.52	—	\$ —
Outstanding at September 30, 2024	<u>1,022,503</u>	\$ 4.67	9.06	\$ —
Exercisable at September 30, 2024	904,853	\$ 5.03	8.97	\$ —

(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, 2023 and September 30, 2024; respectively.

As of September 30, 2024, an aggregate of 1,022,503 shares of common stock are covered by outstanding option awards and 3,664 shares of common stock are available for future awards under the Incentive Plan.

Total compensation cost related to stock options was \$330,802 and \$402,805 for the three months ended September 30, 2024 and 2023, respectively. Total compensation cost related to stock options was \$458,365 and \$546,399 for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, there was \$195,296 of unrecognized compensation costs related to stock options, which is expected to be recognized over a weighted average period of less than one year.

11. License and Royalty Agreements

Inspirevax License

On February 23, 2023, the Company entered into a Commercial License Agreement (the “Inspirevax License Agreement”) for its vaccine product candidate 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. As of September 30, 2024, none of the milestone payment obligations for the Inspirevax License Agreement have been met.

12. Commitments and Contingencies

Three-Way Collaborative Agreement

In May of 2023, the Company entered into a Collaborative Research Agreement (the “Collaboration”) with Inspirevax, and the National Research Council (the “Collaborators”) for research related to the Company’s vaccine product candidate. 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. As part of the Company’s efforts to focus financial resources to the development of its new lead asset, ONP-002, as of September 30, 2024, the Company has suspended its participation in the three-way agreement until additional financial resources can be allocated for the vaccine related research project.

Ladenburg Thalmann Litigation

On December 7, 2022, the Company entered into an investment banking engagement letter with Ladenburg Thalmann, (“Ladenburg”). The engagement letter was subsequently amended at various times (together with amendments to the “Engagement Letter”). The Company terminated the Engagement Letter as of August 15, 2023. Ladenburg sent the Company an invoice in the amount of \$2,500,000, and a demand letter from Ladenburg’s general counsel demanding payment thereof followed shortly thereafter. Ladenburg is of the view that a fee is owed based on the Company’s purchase of assets from Odyssey Health, Inc. The Company strongly disagrees that any such fee is due to Ladenburg and initiated a confidential action for arbitration against Ladenburg with the Financial Industry Regulatory Authority (“FINRA”) on March 12, 2024, seeking, among other things, a declaratory judgment that no such fee is owed. On April 17, 2024 Ladenburg filed a Complaint in federal court in the Southern District of Florida, and also filed motion for a temporary restraining order (“TRO”) and preliminary injunction seeking to move the venue from FINRA to the federal court in Miami-Dade County. On May 3, 2024 the Magistrate Judge assigned to the case issued a Report and Recommendation denying the motion; although Ladenburg objected to the Report and Recommendation, Magistrate Judge’s Report and Recommendation, the District Court Judge adopted the Report and Recommendation, finalizing the Court’s denial of the requested injunctive relief. On May 9, 2024, the Company filed a motion to dismiss in the federal court action, which is still currently pending. Meanwhile, the FINRA action continues and is set to be heard in February of 2025. The Company believes Ladenburg’s claims are unlikely to prevail and intends to defend itself vigorously. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact the Company’s business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that the Company will prevail. The Company does not include an estimate of legal fees and other related defense costs in its estimate of loss contingencies.

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

The following information should be read in conjunction with the Condensed 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, 2023 filed on March 29, 2024.

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 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

Oragenics, Inc. (the "Company" or "we", or "our") was incorporated in November 1996. We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications and vaccines.

Commencing in December of 2023, we are focused on the development of medical products that treat brain related illnesses and diseases and our lead product candidate is for the development, requisite clinical trials and commercialization of ONP-002 for the treatment of mild traumatic brain injury ("mTBI" or "Concussion").

Prior to the purchase of our lead asset ONP-002, starting in May 2020 and through December 31, 2023 our lead asset was a nasal delivery vaccine candidate to provide long-lasting immunity from SARS-CoV-2, which causes COVID-19.

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.

Currently research and development activities related to the nasal vaccine platform and our lantibiotic program are inactive, and we will evaluate alternative opportunities for these programs moving forward as we continue to strengthen our focus and expertise on our intranasal drug delivery platform and drug candidates.

About Mild Traumatic Brain Injury (mTBI)

Concussions are an unmet medical need that affects millions worldwide. Repetitive concussions are thought to increase the risk of developing Chronic Traumatic Encephalopathy ("CTE") and other neuropsychiatric disorders. It is estimated that between 3.5 million and 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.

Our ONP-002 Neurology Asset for Brain Related Illness and Injury

Following our December 2023 acquisition of certain assets from Odyssey Health, Inc. (“Odyssey”) related to the segment of Odyssey’s business focused on developing medical products that treat brain related illnesses and diseases (the “Neurology Assets”) our lead product and focus is on the development and commercialization of ONP-002 for the treatment of mTBI.

ONP-002 to date has been shown to be stable up to 104 degrees for 18-months. The drug candidate is spray-dry manufactured into a powder and filled into the novel intranasal device. The drug is then administered through the nasal passage from a unique nasal delivery device. The novel intranasal device is lightweight and intended to be easy enough for self-administration use in the field or by medical personnel.

We believe the proprietary powder formulation and intranasal administration allows for rapid and direct accessibility to the brain. The device is breath propelled and we expect it to allow patients to blow into the device which closes the soft palate in the back of the nasopharynx, preventing the flow of drug to the lungs or esophagus, minimizes system exposure and side effects, and easily crosses the blood brain barrier. This mechanism traps ONP-002 in the nasal cavity allowing for more abundant and faster drug availability in the traumatized brain.

Expected ONP-002 Product Development Timeline:

<u>Pre-clinical Animal Studies</u>	<u>Phase 1</u>	<u>Phase 2a</u>	<u>Phase 2b</u>	<u>Phase 3</u>
Complete	Complete	Estimated Q4 2024 start	Estimated Q1/Q2 2025 start	Estimated Q4 2026 start

This product development plan is an estimate and is subject to change based on funding, technical risks and regulatory approvals.

Intellectual Property

Patents on ONP-002 have been filed and/or issued and a patent has been filed on the nasal delivery device as follows:

- New chemical entity patent filing concerning the C-20 Steroid compounds has been filed with the USPTO and is pending in the U.S. and approved in Europe and Canada.
 - C-20 steroid compounds, composition and uses thereof to treat traumatic brain injury (TBI), including concussion.
 - Inventions relate to, inter alia, ONP-002 compositions, methods of use to treat, minimize and/or prevent traumatic brain injury (“TBI”), including severe TBI, moderate TBI, and mild TBI, including concussions, methods of manufacture and/or synthesis, products by process, and intermediates.
 - An issued U.S. patent expiration with 5-year maximum patent term extension to 9/17/2040.
 - An issued U.S. patent expiration without patent term extension to 9/17/2035.
- New nasal delivery device filing concerning the Breath-Powered Nasal Devices has been filed with the USPTO as a utility patent application and with the USPTO PCT Receiving Office as a PCT application.
- Breath-Powered Nasal Devices for Treatment of Traumatic Brain Injury (“TBI”), Including Concussion, and Methods.
- Inventions relate to, inter alia, breath-powered nasal devices, single-directional breath-powered nasal devices for providing dual airflow for propelling a drug substance into a nasal cavity for targeted delivery to the olfactory region in high drug substance concentration for rapid diffusion into the brain for the treatment of local or systemic and/or central nervous system (“CNS”) injury, disease or disorder, and methods of treating local or sCNS injury, disease or disorder with such devices.

ONP-002 Pre-Clinical Trials

The drug has completed toxicology studies in rats and dogs. Those studies show that ONP-002 has a large safety margin of its predicted efficacious dose. In preclinical animal studies, the drug demonstrated rapid and broad biodistribution throughout the brain while simultaneously reducing swelling, inflammation, and oxidative stress, along with an excellent safety profile.

Results from the preclinical studies suggest that ONP-002 has an equivalent, and potentially superior, neuroprotective effect compared to related neurosteroids. The animals treated with the drug post-concussion showed positive behavioral outcomes using various testing platforms including improved memory and sensory-motor performance, and reduced depression/anxiety like behavior.

ONP-002 Clinical Trials

ONP-002 has completed a Phase 1 clinical trial in healthy human subjects showing it is safe and well tolerated.

Safety studies have established a dosing regimen of 2X/day for fourteen days. The Phase 1 clinical trial was performed in Melbourne, Australia with a Contract Research Organization (“CRO”), Avance Clinical Pty Ltd (“Avance Clinical”) and Nucleus Network Pty Ltd. The country of Australia provides a currency exchange advantage and a tax rebate at the end of our fiscal year from the Australian government on all Research and Development performed in Australia.

The Phase 1 study was double-blinded, randomized and placebo controlled (3:1, drug: placebo). Phase 1 used a Single Ascending/Multiple Ascending (SAD/MAD) drug administration design. The SAD component was a 1X treatment (low, medium, or high dose) and the MAD component was a 1X/day treatment for five consecutive days (low and medium dose). Blood and urine samples were collected at multiple time points for safety pharmacokinetics. Standard safety monitoring was provided for each body system.

Forty human subjects (31 males, 9 females) were successfully enrolled in Phase 1. The Safety Review Board, made up of medical doctors, has reviewed the trial data and has determined the drug is safe and well tolerated at all dosing levels.

We are preparing for Phase 2 clinical trials to further evaluate ONP-002’s safety and efficacy. Based on the Phase 1 data, we plan to apply for an Investigational New Drug application with the FDA and conduct a Phase 2 trial in the United States.

We anticipate a Phase 2 clinical trial will be performed administering ONP-002 intranasally in concussed patients 2x a day for up to fourteen days. The Phase 2a feasibility study is expected to be performed in Australia with a target initiation date in the fourth quarter of 2024 to be followed closely by a Phase 2b proof of concept study in the US.

Recent Developments – Phase 2

In the nine months ended September 30, 2024, we executed agreements with several vendors to advance our efforts toward starting Phase 2 clinical trials, including a contract with Avance Clinical to conduct Phase 2 clinical trials in Australia.

On August 8, 2024 we announced the successful completion of a study that indicates ONP-002 does not cause cardiotoxicity. Prior to conducting a clinical trial, the U.S. Food and Drug Administration (FDA) requires pharmaceuticals to be tested on cardiac receptors to ensure that they do not show any causes of electrical malformations. Oragenics conducted hERG (human Ether-à-go-go-Related Gene) ion channel studies on ONP-002 under Good Laboratory Practices (GLP) with Charles River Laboratories. Like previous non-GLP hERG studies, inhibitory concentrations were greater than 10 micromolar. Based on Phase I ONP-002 clinical trial dosing and subsequent blood plasma concentrations, ONP-002 is expected to have a large cardiac safety margin, suggesting that ONP-002 treatment for concussion will not cause cardiac arrhythmia.

On August 12, 2024 we announced the successful completion of a study that indicates ONP-002 does not cause DNA damage and genotoxicity in an animal model. Oragenics conducted an *in vivo* (animal) study to determine if multi-day treatments of ONP-002 cause DNA damage and increased risk of cancer. Three concentrations of ONP-002 were used at a low, medium and high dose. Animal bone marrow was dissected and analyzed for DNA damage. The results showed no evidence of genetic mutations, suggesting that ONP-002 does not affect the cell cycle and therefore does not disrupt cell division that could be cancer-causing. Oragenics partnered with VivoPharm, Inc. to conduct this study under Good Laboratory (GLP) conditions. These results suggest that multi-day treatment for concussion using ONP-002 will not cause genotoxicity.

On August 14, 2024 we announced the recent completion of the synthesis of its ONP-002 drug batch for the planned Phase II clinical trial. The company reported 3-month stability with over 99% purity at temperatures ranging from -20°C to 104°C. Oragenics is confident in its belief that ONP-002 will not require cumbersome cold chain protocols during transport and storage, maintaining its chemical structure and function even in extreme temperatures.

Field conditions for contact sports and military operations involve a wide range of temperatures that may affect the stability and effectiveness of drugs intended for acute concussion treatment. ONP-002 has been formulated as a spray-dried powder to improve stability in extreme temperatures. In contrast, narrow temperature storage protocols can be cumbersome and pose greater risk for non-compliance during shipping and field operations.

On August 21, 2024 we announced the completion of our spray-dried formulation and filling in the nasal device for ONP-002. The prefilled formulation is intended to provide the needed drug-device dosing for the planned Phase IIa.

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.

As part of the Company's efforts to preserve cash resources and focus on the development of our ONP-002 concussion drug product candidate, the Company closed its facility in Alachua Florida where some of the work related to the lantibiotics program was performed, and has paused all research and development activities related to our vaccine product candidate. Until the Company can secure additional capital and determine an alternative solution to continue these research and development programs, they will remain paused.

Financial Overview

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 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 \$2,449,234 and \$4,448,623 for the nine months ended September 30, 2024 and 2023, respectively. In 2023 our research and development costs consisted of our COVID vaccine program and our lantibiotics program, which were paused in 2023. For the nine months ended September 30, 2024, our research and development expenses consisted of the costs related to the development of our ONP-002 neurology asset. Due to limited resources, while we continue our development efforts, we have focused our research and development expenses to our ONP-002 drug and paused further development of our vaccine product and lantibiotics research until we can raise additional capital.

Our current product development strategy contemplates continued research and development of our ONP-002 product. 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, 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 candidate is 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. Subject to available capital, overall research and development expenses could increase as a result of our concussion 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 September 4, 2024, we announced the sale of 3 million shares of our common stock and Pre-Funded Warrants to purchase 5 million shares of common stock, par value \$0.001, through a placement agreement with Dawson James Securities, Inc. (“Dawson James”) at an offering price per share of common stock of \$0.55. The offering resulted in gross proceeds of \$4.45 million before deducting placement agent fees and other estimated offering expenses payable by the Company. We also agreed to issue placement agent warrants (“Dawson James Warrants”) to purchase up to 5% of the aggregate number of securities sold in the offering with an exercise price 125% of the offering price of the common stock in the offering. The Dawson James Warrants are exercisable for five years from the date of closing the offering and are initially exercisable six months from the closing of the Offering.

We intend to use the net proceeds from the offering to fund the continued development of ONP-002 and for general corporate purposes and working capital.

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 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.

Results of Operations for the Three and Nine Months Ended September 2024 and 2023

Grant revenue. There was no grant revenue for the three and nine month periods ended September 30, 2024. For the comparable three and nine month periods in 2023, there was \$7,466 and \$37,653 in grant revenue, respectively. 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 \$879,041 and \$2,449,234, respectively, for the three and nine month periods ended September 30, 2024, compared to \$769,350 and \$4,448,623 for the comparable three and nine month periods ended September 30, 2023. This is an increase 14% and a decrease of 45% for the comparable three and nine month periods ended September 30, 2024.

This decrease for the nine month comparable periods was mainly driven by decreased costs associated with the development of our ONP-002 concussion drug as compared to development costs associated with our COVID vaccine product and our lantibiotics program. For the three months ended September 30, 2023, research and development expenses for our COVID vaccine and lantibiotics programs were approximately \$0.8 million and primarily associated with costs for outside consultants. For the three-month period ended September 30, 2024, research and development expense related to ONP-002 was approximately \$0.9 million. For the nine month period ended September 30, 2024 and 2023, respectively our research and development expenses were approximately \$2.4 million for our ONP-002 product and \$4.4 million for our vaccine product and lantibiotics programs.

General and Administrative. General and administrative expenses were approximately \$1.6 million and \$1.3 million for the three months ended September 30, 2024 and 2023 respectively. General and administrative expenses for the nine month period ended September 30, 2024, were approximately \$4.8 million compared to \$3.7 million for the comparable nine month period in 2023, an increase of approximately \$1 million or 29%. This increase was primarily due to increased expenses related to:

- Consulting expenses - \$289,406
- Investor relations - \$526,643
- Salaries, wages, and bonus expense - \$201,820
- Legal expense - \$159,526
- Accounting expense - \$97,406
- Board of Director fees - \$79,785
- Travel expense - \$23,549

These expense increases were offset by decreases in:

- Rent, utilities and other office related expenses - \$275,263 as well as
- Public company, stock compensation, and insurance expenses.

Other Income (Expense). Other income and expense, net, was \$(25,590) for the three months ended September 30, 2024, compared to \$81,561 for the comparable three months in 2023. For the nine month period ended September 30, 2024 and 2023, other income and expense, net, was \$(15,412) and \$200,271 respectively, resulting in a change of \$215,683 or 108% for the comparable nine month periods. The net change was primarily attributable to a reduction in interest income due to lower cash balances in interest earning accounts for the comparable periods.

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, 2024 and 2023, our operating activities used cash of \$6,579,029 and \$6,188,335 respectively. The change is primarily driven by changes in net losses adjusted for non-cash items and changes in operating assets and liabilities. We had a working capital surplus of \$1,986,837 and \$2,067,593 at September 30, 2024 and December 31, 2023, respectively.

During the nine months ended September 30, 2024 and 2023, our financing activities provided cash of \$6,239,577 and \$464,479 respectively. The cash provided by financing activities during the nine months ended September 30, 2024 was primarily due to net proceeds from our underwritten public offerings.

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 a reduction in 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 fourth 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 the Company entered into an ATM with Ladenburg Thalmann & Co. Inc (“Ladenburg”) to sell shares of its common stock. The Company did not issue any shares of common stock under its ATM with Ladenburg during the nine month periods ended September 30, 2024 and 2023. The Company did not sell any shares through the ATM program while it was active. The ATM program with Ladenburg terminated on January 30, 2024.

On August 8, 2024, the Company entered into an At-The-Market Issuance Sales Agreement (the “Sales Agreement”) with Ascendant Capital Markets, LLC, as sales agent (the “Agent”), pursuant to which the Company may offer and sell through or to the Agent (the “ATM”) up to \$10.0 million in shares of its common stock (the “Shares”) at-the-market. Shares offered and sold in the Offering are anticipated to be issued pursuant to the Company’s universal shelf registration statement on Form S-3 (the “Shelf Registration Statement”) filed with the Securities and Exchange Commission (the “SEC”). Under the terms of the Sales Agreement, the Agent is entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares under the Agreement. On October 9, 2024 the Company terminated the Sales Agreement with Ascendant Capital, and there were no shares sold under the Sales Agreement with Ascendant Capital in the nine months ended September 30, 2024.

On October 11, 2024, Oragenics, Inc. (the “Company”) entered into an At-the-Market Sales Agreement (the “Sales Agreement”) with Dawson James Securities Inc. (“Dawson James” or the “Sales Agent”) pursuant to which the Company may issue and sell, from time to time, shares of its common stock (the “Shares”), depending on market demand, with the Sales Agent acting as the sales agent or principal (the “Offering”). Sales of the Shares may be made by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415(a)(4) of the Securities Act of 1933, as amended (the “Securities Act”), including, without limitation, sales made directly on or through the NYSE American. The Agent will use its commercially reasonable efforts to sell the Shares requested by the Company to be sold on its behalf, consistent with the Agent’s normal trading and sales practices, under the terms and subject to the conditions set forth in the Sales Agreement. The Company has no obligation to sell any of the Shares. The Company may instruct the Agent not to sell the Shares if the sales cannot be effected at or above the price designated by the Company from time to time and the Company may at any time suspend sales pursuant to the Sales Agreement. As of November 13, 2024 there were no shares sold under the Sales Agreement with Dawson James.

Previously, on August 8, 2024, the Company entered into an At-The-Market Issuance Sales Agreement (the “Sales Agreement”) with Ascendant Capital Markets, LLC, as sales agent (the “Agent”), pursuant to which the Company may offer and sell through or to the Agent (the “ATM”) up to \$10.0 million in shares of its common stock at-the-market. On October 9, 2024, the Company terminated the Sales Agreement with Ascendant Capital. There were no shares sold under the Sales Agreement with Ascendant Capital in the nine months ended September 30, 2024.

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 2024, we entered into a short-term note payable for \$636,972 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 2024 and continue through May of 2025 based on straight-line amortization over the 10-month period.

Recent Developments

On September 4, 2024, we announced the sale of 3 million shares of our common stock and Pre-Funded Warrants to purchase 5 million shares of common stock, par value \$0.001, through a placement agreement with Dawson James Securities, Inc. (“Dawson James”) at an offering price per share of common stock of \$0.55. The offering resulted in gross proceeds of \$4.45 million before deducting placement agent fees and other estimated offering expenses payable by the Company. We also agreed to issue placement agent warrants (“Dawson James Warrants”) to purchase up to 5% of the aggregate number of securities sold in the offering with an exercise price 125% of the offering price of the common stock in the offering. The Dawson James Warrants are exercisable for five years from the date of closing the offering and are initially exercisable six months from the closing of the Offering.

Our Outstanding Preferred Stock

Series A and Series B

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, 2024 our outstanding Series A and Series B Preferred Stock and the amount of common stock that may be issued upon conversion is set forth below:

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

In addition, we issued warrants to purchase shares of Common Stock to the Series A holders, and to the Series B holders in connection with the Preferred Stock Financing. As of September 30, 2024, there are 17,742 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.

Series F

On December 28, 2023, as part of consideration paid to Odyssey and pursuant to an Asset Purchase Agreement executed with Odyssey, we issued 8,000,000 shares of convertible Series F Preferred Stock. The Series F Preferred Stock is convertible on a one-for-one basis. The Series F Preferred Stock has no voting rights, is ranked junior to our Series A and Series B Preferred Stock and is at parity with our common stock, in addition there shall be no dividends paid on the Series F Preferred Stock. At the closing of the Odyssey transaction 511,308 shares of Series F Preferred Stock were converted into 511,308 shares of common stock. At September 30, 2024, there were 7,488,692 shares of Series F Preferred Stock outstanding.

Future Capital Requirements

On April 18, 2024, we received Notice from the NYSE American that we are no longer in compliance with NYSE American's continued listing standards. Specifically, we are not in compliance with the continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE American Company Guide. Section 1003(a)(ii) requires a listed company to have stockholders' equity of \$4 million or more if the listed company has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. Section 1003(a)(iii) requires a listed company to have stockholders' equity of \$6 million or more if the listed company has reported losses from continuing operations and/or net losses in its five most recent fiscal years. Subsequently, the NYSE American notified the Company that it also is not in compliance with subsection (i) Section 1003(a), which requires stockholders' equity of no less than \$2,000,000 if the Company has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years.

We reported stockholders' equity of \$3.2 million as of December 31, 2023, and \$3 million as of September 30, 2024. Additionally, we have reported losses from continuing operations and/or net losses in our five most recent fiscal years ended December 31, 2023.

The Notice further provides that we must submit a plan of compliance (the "Plan") by May 18, 2024 (the "Deadline") addressing how we intend to regain compliance with the continued listing standards by October 18, 2025. The Plan is required to include specific milestones, quarterly financial projections and details related to any strategic initiatives we plan to complete.

We submitted the Plan by the Deadline and on June 18, 2024 we were notified by the NYSE American that our Plan to regain compliance with NYSE American's continued listing standards had been accepted. As part of the acceptance we were granted a plan period through October 18, 2025 to regain compliance. During the plan period, we will be subject to quarterly monitoring for compliance with the plan. If we do not regain compliance with NYSE American's listing standards by October 18, 2025, or if we do not make progress consistent with our plan, the NYSE American may initiate delisting proceedings.

Our common stock will continue to be listed on NYSE American during the plan period under the symbol "OGEN" with a "below compliance" indicator appended to our ticker symbol (with the added designation of ".BC"). Our receipt of the notification from NYSE American accepting the compliance Plan does not affect our business operations or our reporting requirements with the U.S. Securities and Exchange Commission.

We are committed to undertaking a transaction or transactions in the future to achieve compliance with the NYSE American's requirements. However, there can be no assurance that we will be able to achieve compliance with the NYSE American's continued listing standards within the required timeframe. Additionally, we can provide no assurance that the transaction or transactions necessary to achieve compliance can be obtained or that they can be obtained with terms favorable to investors.

If the Common Stock ultimately were to be delisted for any reason, it could negatively impact the Company by (i) reducing the liquidity and market price of the Company's Common Stock; (ii) reducing the number of investors willing to hold or acquire the Common Stock, which could negatively impact the Company's ability to raise equity financing; and (iii) limiting the Company's ability to use a registration statement to offer and sell freely tradable securities, thereby preventing the Company from accessing the public capital markets; and (iv) impairing the Company's ability to provide equity incentives to its employees.

Our capital requirements for the remainder of 2024 will depend on numerous factors, including our ability raise additional capital including through possible joint ventures and/or partnerships. We expect to incur substantial expenditures to further develop or commercialize 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 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 financing plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our current available cash and cash equivalents provide us with limited liquidity. We believe our existing cash will allow us to fund our operating plan through the fourth quarter of 2024. As a result, we have implemented certain cost-saving initiatives, including reducing our efforts and staff focused on our antibiotics program and our vaccine product candidate, which are expected to negatively impact the development of these programs. 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 ONP-002 we will require additional capital. In addition, we continue to pursue other non-dilutive opportunities for our 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 ONP-002 concussion candidate at our currently anticipated pace, 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.

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

- Conducting preclinical research and phase 2 clinical trials for our ONP-002 concussion drug,
- 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 candidate, 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;
- The costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- The timing, receipt and amounts of sales of, or royalties on, our products and future products,

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 condensed 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 condensed 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 condensed 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.

Recently Issued Accounting Pronouncements

There are no accounting pronouncements issued or effective during the three months ended September 30, 2024 that have had or are expected to have an impact on our condensed 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 President and Interim Principal Executive Officer and Chief Financial Officer. The purpose of disclosure controls and procedures is to ensure that information required to be disclosed in the reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management, including our President and Interim Principal Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures. Based upon that evaluation, our Interim Principal Executive Officer and Chief Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures were effective as of September 30, 2024 in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported with the time periods specified in the Securities and exchange Commission’s rules and forms.

Changes in Internal Controls over Financial Reporting

Our management, with the participation of our President and Interim Principal Executive Officer 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.

Limitations on the Effectiveness of Controls

Our management, including our Interim Principal 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

On December 7, 2022, the Company entered into an investment banking engagement letter with Ladenburg Thalmann, (“Ladenburg”). The engagement letter was subsequently amended at various times (together with amendments to the “Engagement Letter”). The Company terminated the Engagement Letter as of August 15, 2023. Ladenburg sent the Company an invoice in the amount of \$2,500,000, and a demand letter from Ladenburg’s general counsel demanding payment thereof followed shortly thereafter. Ladenburg is of the view that a fee is owed based on the Company’s purchase of assets from Odyssey Health, Inc. The Company strongly disagrees that any such fee is due to Ladenburg and initiated a confidential action for arbitration against Ladenburg with the Financial Industry Regulatory Authority (“FINRA”) on March 12, 2024, seeking, among other things, a declaratory judgment that no such fee is owed. On April 17, 2024 Ladenburg filed a Complaint in federal court in the Southern District of Florida, and also filed motion for a temporary restraining order (“TRO”) and preliminary injunction seeking to move the venue from FINRA to the federal court in Miami-Dade County. On May 3, 2024, the Magistrate Judge assigned to the case issued a Report and Recommendation denying the motion; although Ladenburg objected to the Report and Recommendation, Magistrate Judge’s Report and Recommendation, the District Court Judge adopted the Report and Recommendation, finalizing the Court’s denial of the requested injunctive relief. On May 9, 2024, the Company filed a motion to dismiss in the federal court action, which is still currently pending. Meanwhile, the FINRA action continues and is set to be heard in February of 2025. The Company believes Ladenburg’s claims are unlikely to prevail and intends to defend itself vigorously. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact the Company’s business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that the Company will prevail. The Company does not include an estimate of legal fees and other related defense costs in its estimate of loss contingencies.

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, 2023 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, 2023 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, 2023 filed on March 29, 2024. 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 \$7.2 million and \$7.9 million for the nine months ended September 30, 2024 and 2023, respectively, and approximately \$21 million for the year ended December 31, 2023. As of September 30, 2024, our accumulated deficit was approximately \$213 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 phase 2 clinical trials, contract manufacturing and file an IND for our concussion 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 COVID vaccine candidate and our antibiotics 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 our accumulated losses and substantial doubt that we can continue as a going concern beyond December 2024, the Company is evaluating various opportunities for its Antibiotics Program and its N-CoV2-1 vaccine product candidate, as well as alternative assets that could be acquired or developed. These opportunities could include a wide range of options including, among other things, a potential sale, spin-off, fund raising, combination or other strategic transaction, which may also include the winding down of research and development activities. The result of this process may result in the liquidation of assets for significantly less than amounts that have been invested in them, the write-off of prior expenses incurred in connection with the development of such assets and may have a material adverse effect on our results of operations and liquidity. Notwithstanding the above, the Company will seek to maximize the value of such assets to the extent possible. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate or government collaboration and licensing arrangements. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete existing nonclinical and planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. We believe our existing cash will allow us to fund our operating plan only through the fourth quarter of 2024.

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.

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 as we continue our work research and development activities and preparation to start phase 2 clinical trials for ONP-002. 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, with limited capital, we expect to continue to hold research and development of our antibiotics and Covid programs and may reduce or slow research and development activity of our ONP-002 lead asset. Thus, the unavailability of capital could substantially harm our business, results of operations and financial condition.

With limited resources we have paused our other product candidate research and development and now rely on the progress and success of ONP-002.

With limited capital, we have put the research and development of our COVID vaccine program and our antibiotics program on hold and have chosen instead to focus the limited capital on the development of ONP-002. As such, our future success currently depends on the successful development of ONP-002, our concussion asset, of which there can be no assurances.

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

We currently have a very small management team. Our success is dependent upon the ability, expertise and judgment of our senior management and consultants. 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. Mr. Redmond continues to serve as President and CEO of Odyssey, which may give rise to conflicts of interest.

We believe that our future success with regard to the Neurology Assets depends on the skills and efforts of our senior management and other key personnel, including Jacob VanLandingham, Ph.D., one of the Company's independent contractors. The loss of the services of any of these individuals could harm our ability to successfully pursue the development of the Neurology Assets. If any of our executive officers or key personnel left or was otherwise 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.

On December 5, 2022, the Mississippi Department of Human Services ("MDHS") filed an Amended Complaint in the Circuit Court of Hinds County, Mississippi First Judicial District against Mississippi Community Education Center, Inc., a non-profit corporation, Nancy New, its director, Prevacus, Dr. VanLandingham its founder, and several other defendants, alleging, among other things, a conspiracy to defraud the MDHS. Prevacus, Inc., is the Company from whom Odyssey purchased the Neurology Assets in 2021. The MDHS is designated by Mississippi law as the State agency exclusively responsible for administering the federally-authorized and federally-funded anti-poverty (or "welfare") program known as the Temporary Assistance for Needy Families program, or "TANF." With regard to Prevacus and Dr. VanLandingham, the complaint alleges that \$2.1 million was funneled through the Mississippi Community Education Center, a nonprofit run by Nancy New, to Prevacus and PresolMD, another company founded by Dr. VanLandingham. The MDHS, among other things, is seeking to recover \$2.1 million it alleges went to Prevacus and PresolMD. Prevacus and Dr. VanLandingham have denied any wrongdoing and have denied being aware that the funds received from Community Education Center, Inc. were TANF funds. However, recently, Dr. VanLandingham plead guilty to one federal charge of wire fraud in connection with this case and is awaiting sentencing, the timing and results of which are uncertain. The Company does not believe it has any financial exposure related to the reimbursement of the funds paid to Prevacus and does not believe there are any grounds on which the Company could become embroiled in the foregoing legal proceedings. Dr. VanLandingham is not an Officer or Director of Orogenics but is instead an independent contractor. Nevertheless, any negative media related to foregoing legal proceedings, and in particular any negative media related to the Neurology Assets or Dr. VanLandingham, may negatively impact the Company's ability to raise capital and otherwise continue the development of the Neurology Assets. Furthermore, while the Company has relationships with other experts in the field, including Frank Peacock, MD, the Company's Chief Clinical Officer, Dr. VanLandingham's ability to continue to assist in the development of the Neurology Assets may be negatively impacted by the foregoing legal proceedings which could negatively impact the Company's ability to raise capital and otherwise continue the development of the Neurology Assets.

Risks Related to Our Common Stock

We cannot assure you that we will continue to be listed on the NYSE American.

Our common stock commenced trading on the NYSE American (formerly the NYSE MKT) on April 10, 2013, and we are subject to certain NYSE American continued listing requirements and standards. On April 18, 2024 we received notification (the “Notice”) from the NYSE American that we were no longer in compliance with NYSE American’s continued standards. Specifically, the letter stated that the Company was in compliance with the continued listing standards set forth in Sections 1003(a)(ii) and 1003(a)(iii) of the NYSE American Company Guide (the Company Guide”). Section 1003(a)(ii) requires a listed company to have stockholders’ equity of \$4 million or more if the listed company has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. Section 1003(a)(iii) requires a listed company to have stockholders’ equity of \$6 million or more if the listed company has reported losses from continuing operations and/or net losses in its five most recent fiscal years. On August 13, 2024, we received a second notice from the NYSE American LLC informing us that we also are not in compliance with subsection (i) of Section 1003(a), which requires stockholders’ equity of no less than \$2,000,000 if the Company has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years. We reported stockholders’ equity of \$3.2 million as of December 31, 2023, and \$3 million as of September 30, 2024. Additionally, we have reported losses from continuing operations and/or net losses in our five most recent fiscal years ended December 31, 2023. On May 17, 2024, we submitted a plan of compliance (the “Plan”) to the NYSE American. On June 18, 2024, the NYSE American accepted our Plan; the Company will be able to continue its listing during the Plan period and will be subject to continued periodic review by the NYSE American staff. If we are not in compliance with the continued listing standards by October 18, 2025, or if the Company does not make progress consistent with the Plan during the Plan period, the Company will be subject to delisting procedures as set forth in the NYSE American Company Guide. The Company is committed to undertaking a transaction or transactions in the future to achieve compliance with the NYSE American’s requirements. However, there can be no assurance that the Company will be able to achieve compliance with the NYSE American’s continued listing standards within the required timeframe. Further, the Company may fall out of compliance with other provisions of the NYSE American continued listing requirements and standards, including with regard to the Company’s stock price. If the Common Stock ultimately were to be delisted for any reason, it could negatively impact the Company by (i) reducing the liquidity and market price of the Company’s Common Stock; (ii) reducing the number of investors willing to hold or acquire the Common Stock, which could negatively impact the Company’s ability to raise equity financing; (iii) limiting the Company’s ability to use a registration statement to offer and sell freely tradable securities, thereby preventing the Company from accessing the public capital markets; and (iv) impairing the Company’s ability to provide equity incentives to its employees.

The issuance of additional equity securities by us in the future would result in dilution to our existing common shareholders.

Our Board of Directors has authority, without action or vote of our shareholders, to issue all or a part of our authorized but unissued shares, except where shareholder approval is required by law or the rules of any exchange on which our shares are listed. Any issuance of additional equity securities by us in the future could result in dilution to our existing common shareholders. Such issuances could be made at a price that reflects a discount or a premium to the then-current trading price of our common stock. In addition, our business strategy may include expansion through internal growth by acquiring complementary businesses, acquiring or licensing additional products or brands, or establishing strategic relationships with targeted customers and suppliers. In order to do so, or to finance the cost of our other activities, we may issue additional equity securities that could result in further dilution to our existing common shareholders. These issuances would dilute the percentage ownership interest of our existing common shareholders, which would have the effect of reducing their influence on matters on which our shareholders vote and might dilute the book value of our common stock. For example, our outstanding shares of common stock at December 31, 2023 was 3,080,693, due to additional common stock issuances related to capital raises, at September 30, 2024 our outstanding shares of common stock was 9,387,547. Furthermore, if Odyssey or the holders of Preferred Shares Series A and B convert their preferred shares into common stock an additional 7,511,220 shares of common stock could be issued resulting in dilution to our existing common shareholders. Additionally, as of November 13, 2024, 1,139,705 Pre-Funded Warrants remain unexercised.

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

- (a) None.
- (b) None.
- (c) **Director and Officer Trading Plans and Arrangements.** During the quarterly period ended September 30, 2024, no director or officer of the Company adopted or terminated any contract, instruction or written plan for the purchase or sale of securities of the Company intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) of the Exchange Act or any “non-Rule 10b5-1 trading arrangement” (as defined in the Exchange Act).
- (d)

ITEM 6. EXHIBITS

Incorporated by reference to Exhibits filed after signature page.

EXHIBIT INDEX

Exhibit number	Exhibit description	Incorporated by Reference				Filed herewith
		Form	File no.	Exhibit	Filing date	
1.1	Placement Agency Agreement dated June 25, 2024 between Oragenics, Inc. and Dawson James Securities, Inc.	8-K	001-32188	1.1	6/26/24	
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	001-32188	3.1	1/23/23	
3.7	Amendment to Articles of Incorporation for Certificate of Designation of Series F Convertible Preferred Stock	8-K	001-32188	3.1	12/8/23	
3.8	Amendment to Articles of Incorporation to Increase Common Stock	8-K	001-32188	3.1	12/15/23	
3.9	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.10	First Amendment to Bylaws	8-K	001-32188	3.1	6/9/10	
3.11	Second Amendment to Bylaws	8-K	001-32188	3.1	8/24/10	
3.12	Third Amendment to Bylaws	8-K	001-32188	3.9	2/28/22	

10.1	<u>At-the-Market Sales Agreement (the "Sales Agreement") between the Company and Dawson James Securities Inc. dated October 11, 2024</u>	8-K	001-32188	1.1	10/15/24	
31.1	<u>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.</u>					X
31.2	<u>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.</u>					X
32.1	<u>Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (Chief Executive Officer). **</u>					X
32.2	<u>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). **</u>					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 13th day of November 2024.

ORAGENICS, INC.

BY: /s/ J. Michael Redmond
J. Micheal Redmond, President and Interim Principal Executive Officer

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

CERTIFICATION

I, J. Michael Redmond, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Orogenics, 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 13, 2024

By: /s/ J. Michael Redmond

J. Michael Redmond

President and Interim Principal Executive Officer

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 13, 2024

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

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, 2024 (the "Report") of Oragenics, Inc. (the "Registrant"), as filed with the Securities and Exchange Commission on the date hereof, I, J. Michael Redmond, 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/ J. Michael Redmond

Name: J. Michael Redmond
President and Interim Principal Executive Officer

Date: November 13, 2024

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, 2024 (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 13, 2024
