

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

**Form 10-Q**

(Mark One)

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

For the quarterly period ended March 31, 2025  
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 No. 001-32188

**ORAGENICS, INC.**

(Exact name of registrant as specified in its charter)

Florida  
(State or other jurisdiction of  
incorporation or organization)

59-3410522  
(I.R.S. Employer  
Identification No.)

1990 Main Street, Suite 750  
Sarasota, Florida 34236  
(Address of principal executive offices, including zip code)

(813) 286-7900  
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each Class	Trading Symbol	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 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 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, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "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

21,475,289 shares of common stock, par value \$0.001 per share, outstanding as of May 9, 2025.

ORAGENICS, INC.  
FORM 10-Q  
For the Quarter Ended March 31, 2025

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

**Oragenics, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**

	<u>March 31,</u> <u>2025</u>	<u>December 31,</u> <u>2024</u>
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 3,421,078	\$ 864,840
Prepaid expenses and other current assets	448,033	607,670
Total current assets	<u>3,869,111</u>	<u>1,472,510</u>
Total assets	<u>\$ 3,869,111</u>	<u>\$ 1,472,510</u>
<b>Liabilities and Shareholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 1,177,038	\$ 1,355,867
Short-term notes payable, net of debt issuance costs	2,554,385	328,528
Total liabilities	<u>3,731,423</u>	<u>1,684,395</u>
Shareholders' equity (deficit):		
Preferred stock, no par value; 50,000,000 shares authorized; 7,488,692 and 7,488,692 Series F shares and 1,000,000 and -0- Series G outstanding at March 31, 2025 and December 31, 2024, respectively	-	-
Common stock, \$0.001 par value; 350,000,000 shares authorized and 21,475,289 and 12,570,100 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	21,475	12,570
Additional paid-in capital	219,119,378	216,561,717
Accumulated deficit	<u>(219,003,165)</u>	<u>(216,786,172)</u>
Total shareholders' equity (deficit)	<u>137,688</u>	<u>(211,885)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 3,869,111</u>	<u>\$ 1,472,510</u>

*The accompanying notes are an integral part of these unaudited consolidated financial statements.*

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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2025</b>	<b>2024</b>
Operating expenses:		
Research and development	\$ 341,542	\$ 663,414
General and administrative	1,684,685	1,796,689
Total operating expenses	<u>2,026,227</u>	<u>2,460,103</u>
Loss from operations	(2,026,227)	(2,460,103)
Other income (expense):		
Interest income	10,203	19,235
Interest expense	(199,127)	(7,085)
Foreign currency exchange net	(1,842)	(2,880)
Total other income, net	<u>(190,766)</u>	<u>9,270</u>
Loss before income taxes	<u>(2,216,993)</u>	<u>(2,450,833)</u>
Income tax benefit	—	—
Net loss	<u>\$ (2,216,993)</u>	<u>\$ (2,450,833)</u>
Basic and diluted net loss per share	<u>\$ (0.12)</u>	<u>\$ (0.70)</u>
Shares used to compute basic and diluted net loss per share	<u>18,216,227</u>	<u>3,496,078</u>

*The accompanying notes are an integral part of these unaudited consolidated financial statements.*

**Oragenics, Inc.**  
**Condensed Consolidated Statements of Stockholders' Equity (Deficit)**  
**(Unaudited)**

	<b>Common Stock</b>		<b>Preferred Stock</b>		<b>Additional Paid In Capital</b>	<b>Accumulated Deficit</b>	<b>Total Shareholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>			
Balances at December 31, 2024	<u>12,570,100</u>	<u>\$ 12,570</u>	<u>7,488,692</u>	<u>\$ —</u>	<u>\$ 216,561,717</u>	<u>\$(216,786,172)</u>	<u>\$ (211,885)</u>
Compensation expense relating to options	—	—	—	—	17,706	—	17,706
Compensation expense recapture relating to options	—	—	—	—	(86,470)	—	(86,470)
Sale of Common Stock	7,765,484	7,765	—	—	2,626,425	—	2,634,190
Conversion of prefunded warrants to common stock	1,139,705	1,140	—	—	—	—	1,140
Issuance of Series G Preferred Stock	—	—	1,000,000	—	—	—	—
Net loss	—	—	—	—	—	(2,216,993)	(2,216,993)
Balances at March 31, 2025	<u>21,475,289</u>	<u>\$ 21,475</u>	<u>8,488,692</u>	<u>\$ —</u>	<u>\$ 219,119,378</u>	<u>\$(219,003,165)</u>	<u>\$ 137,688</u>
	<b>Common Stock</b>		<b>Preferred Stock</b>		<b>Additional Paid In Capital</b>	<b>Accumulated Deficit</b>	<b>Total Shareholders' Equity</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>			
Balances at December 31, 2023	<u>3,080,693</u>	<u>\$ 3,081</u>	<u>16,955,692</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	1,399	—	—	1,837,201	—	1,838,600
Net loss	—	—	—	—	—	(2,450,833)	(2,450,833)
Balances at March 31, 2024	<u>4,480,693</u>	<u>\$ 4,480</u>	<u>16,955,692</u>	<u>\$ 1,592,723</u>	<u>\$ 209,697,149</u>	<u>\$(208,669,087)</u>	<u>\$ 2,625,265</u>

*The accompanying notes are an integral part of these unaudited consolidated financial statements.*

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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2025</b>	<b>2024</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (2,216,993)	\$ (2,450,833)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and closing costs	192,859	-
Stock-based compensation expense	17,706	69,344
Stock-based compensation recapture expense	(86,470)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	159,637	11,061
Operating lease right of use assets	-	9,811
Accounts payable and accrued expenses	(178,829)	(693,821)
Change in operating lease liabilities	-	(9,811)
Net cash used in operating activities	(2,112,090)	(3,064,249)
<b>Cash flows from financing activities:</b>		
Borrowings on short-term notes payable	2,228,563	-
Payments on short-term notes payable	(195,565)	(185,863)
Net proceeds from issuance of common stock	2,635,330	1,838,600
Net cash provided by financing activities	4,668,328	1,652,737
Net decrease in cash and cash equivalents	2,556,238	(1,411,512)
Cash and cash equivalents at beginning of period	864,840	3,483,501
Cash and cash equivalents at end of period	\$ 3,421,078	\$ 2,071,989
<i>Supplemental disclosure of cash flow information:</i>		
Interest paid	\$ 6,268	\$ 7,085

*The accompanying notes are an integral part of these unaudited consolidated financial statements.*

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

**Note 1. Basis of Presentation and Nature of Operations**

***Basis of Presentation***

The accompanying condensed consolidated financial information of Oragenics, Inc. and its wholly-owned subsidiary Noachis Terra Inc. is unaudited and has been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) and pursuant to the rules and regulations of the Securities and Exchange Commission (“SEC”). All intercompany balances and transactions have been eliminated. However, such information reflects all adjustments, consisting only of normal recurring adjustments, which are, in the opinion of management, necessary for a fair presentation of the consolidated financial position, results of operations and cash flows for the interim periods. The consolidated financial information as of December 31, 2024 is derived from our 2024 Annual Report on Form 10-K. The consolidated financial statements included herein should be read in conjunction with the consolidated financial statements and the notes thereto included in our 2024 Annual Report on Form 10-K filed with the SEC on March 14, 2025. The consolidated results of operations for the interim periods presented are not necessarily indicative of the results to be expected for the full year.

***Significant Accounting Policies***

Our significant accounting policies have not changed during the three months ended March 31, 2025 from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024.

***Nature of Operations***

We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications in neurology and fighting infectious diseases. We currently 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”).

***Going Concern***

In light of our recurring losses, accumulated deficit and negative cash flow, the report of our independent registered public accounting firm on our consolidated financial statements for the year ended December 31, 2024 contained an explanatory paragraph raising substantial doubt about our ability to continue as a going concern.

We have incurred losses and negative cash flows from operations since inception. To date, we have not generated significant revenues from operations. We incurred a net loss of \$2.2 million and used cash of \$2.1 million in our operating activities during the three months ended March 31, 2025 and, as of March 31, 2025, we had an accumulated deficit of \$219 million.

Historically, our major sources of cash have been comprised of proceeds from various public and private offerings of our common stock and preferred stock, warrant exercises, income earned on grants and interest income. During the first quarter of 2025, we raised \$2.6 million in net proceeds from private placements and sales of our common stock and \$2.2 million from the issuance of debt, net of issuance costs.

We expect to incur substantial expenditures to further develop our concussion drug. We believe the working capital at March 31, 2025 will be sufficient to meet our business objectives through the third quarter of 2025.

These matters, when considered in the aggregate, raise substantial doubt about our ability to continue as a going concern for a reasonable period of time, which is defined as within one year after the date that our consolidated financial statements are issued.

Additional financing will be required to continue operations after we exhaust our current cash resources and to continue our long-term plans for clinical trials and new product development. There can be no assurance that any such financing can be realized or, if realized, what the terms thereof may be, or that any amount that we are able to raise will be adequate to support our working capital requirements until we achieve profitable operations.

## Note 2. New Accounting Pronouncements

### ASU 2023-09

In December 2023, the FASB issued ASU 2023-09 related to improvements to income tax disclosures. The amendments in this update require enhanced jurisdictional and other disaggregated disclosures for the effective tax rate reconciliation and income taxes paid. The amendments in this update are effective for fiscal years beginning after December 15, 2024. We plan to adopt this pronouncement and make the necessary updates to our disclosures for the year ending December 31, 2025, and, aside from these disclosure changes, we do not expect the amendments to have a material effect on our financial statements.

### ASU 2024-03

In November 2024, the FASB issued ASU 2024-03 related to the disaggregation of certain income statement expenses. The amendments in this update require public entities to disclose incremental information related to purchases of inventory, team member compensation and depreciation, which will provide investors the ability to better understand entity expenses and make their own judgements about entity performance. The amendments in this update are effective for fiscal years beginning after December 15, 2026. We plan to adopt this pronouncement and make the necessary updates to our disclosures for the year ending December 31, 2027, and, aside from these disclosure changes, we do not expect the amendments to have a material effect on our financial statements.

## Note 3. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	March 31, 2025	December 31, 2024
Prepaid research and development	\$ 208,126	\$ 177,437
Prepaid insurance	177,234	354,467
Other	62,673	75,766
	<u>\$ 448,033</u>	<u>\$ 607,670</u>

## Note 4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses consisted of the following:

	March 31, 2025	December 31, 2024
Accounts payable trade	\$ 772,498	\$ 1,144,634
Accrued vacation and PTO	6,106	8,399
Accrued expenses	398,434	202,834
	<u>\$ 1,177,038</u>	<u>\$ 1,355,867</u>

## Note 5. Short-Term Notes Payable

On March 13, 2025, we issued a \$3.0 million promissory note (the "Note") to a single investor at an original issue discount of 17%. Net proceeds to us were \$2.25 million after placement agent fees of \$175,000 and legal expenses of \$98,437.

No interest accrues on the Note unless an event of default occurs, at which time interest will accrue at a rate of 20% per annum. The Note matures upon the earlier of July 14, 2025 or the closing of any subsequent offering by us with net proceeds equal to or in excess of all amounts due under the Note.

The Note contains certain Events of Default, including (i) our failure to pay any amount of principal, interest, redemption price or other amounts due under the Note or any other transaction document, (ii) any default under, redemption of, or acceleration prior to maturity of any indebtedness, as such term is defined in the transaction documents, (iii) bankruptcy, (iv) a final judgement or judgements for the payment of money in excess of \$250,000 which is not discharged or stayed pending appeal within 60 days, and (v) any breach or failure to comply with any provision of the Note or any other transaction document.



In connection with the issuance of the Note, we designated and issued 1,000,000 shares of our authorized but unissued shares of preferred stock as Series G Mirroring preferred stock. For a description of the principal terms of the Series G Mirroring preferred stock, see Note 8.

We intend to use the net proceeds from the Note for working capital and other general corporate purposes.

Short-term notes payable consisted of the following:

	March 31, 2025	December 31, 2024
Insurance premium financing of \$636,972 and \$611,109 due in monthly installments of \$67,277 and \$4,366 which includes principal and annual interest at 9.55% through May 24, 2025 and May 24, 2024, respectively	\$ 132,963	\$ 328,528
\$3.0 million non-interest bearing promissory note due July 14, 2025	3,000,000	-
	<u>3,132,963</u>	<u>-</u>
Unamortized debt issuance costs and original issue discount	(578,578)	-
	<u>\$ 2,554,385</u>	<u>\$ 328,528</u>

## Note 6. Stock-Based Compensation

### 2021 Equity Incentive Plan

Our 2021 Equity Incentive Plan (the "2021 Plan") authorizes the grant of stock options (incentive and non-statutory), stock appreciation rights and restricted stock covering a total of 3,166,667 shares of our common stock. Options are granted at the fair value of our common stock on the date of grant and generally vest either immediately or over a period of up to three years from the date of grant and expire 10 years from the date of grant. As of March 31, 2025, 769,888 shares were reserved for issuance related to the 2021 Plan and 2,257,279 shares of our common stock remain available for awards.

### Stock Option Activity

Stock option activity was as follows:

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	993,753	\$ 4.65	6.72	\$ -
Canceled or expired	(223,865)	3.92		
Outstanding at March 31, 2025	<u>769,888</u>	4.87	7.76	-
Exercisable at March 31, 2025	<u>734,888</u>	\$ 5.08	7.36	\$ -

The canceled or expired options of 223,865 relate to the forfeiture of stock options.

### Unrecognized Stock-Based Compensation Costs

As of March 31, 2025, unrecognized stock-based compensation was \$13,780, which will be recognized over an average expected recognition period of .47 years.

## Note 7. Warrants

Outstanding and exercisable warrants as of March 31, 2025 are presented below:

Warrants Outstanding	Exercise Price	Expiration Date
153,334	\$ 75.00	5/1/2025
52,911	\$ 60.00	7/17/2025
70,000	\$ 1.88	2/27/2029
55,000	\$ 1.25	6/29/2029
<u>405,329</u>	<u>\$ 0.69</u>	<u>9/4/2029</u>
<u>736,574</u>		

## **Note 8. Shareholders' Equity**

### ***At-The-Market Sales Agreement with Dawson James***

On October 11, 2024, we entered into an At-the-Market Sales Agreement (the "ATM Agreement") with Dawson James Securities Inc. ("Dawson James") pursuant to which are allowed to issue and sell, from time to time, shares of our common stock (the "Shares"). Dawson James uses its commercially reasonable efforts to sell the Shares requested by us to be sold, consistent with their normal trading and sales practices. We may instruct Dawson James not to sell the Shares if the sales cannot be effected at or above the price designated by us and we may suspend sales pursuant to the ATM Agreement at any time. We pay Dawson James a commission of up to 3.0% of the gross proceeds from the sale of Shares under the ATM.

In February 2025, we sold 7.8 million shares pursuant to the ATM Agreement for net proceeds of \$2.6 million after commissions and legal expenses totaling \$0.11 million.

### ***Series A Convertible Preferred Stock***

On May 10, 2017, and on July 25, 2017, we issued 12,000,000 shares of convertible preferred stock designated as Series A Convertible preferred stock for an original purchase price and initial liquidation preference of \$3.0 million. Each share of Series A Convertible preferred stock was issued for \$0.25 per share. On March 9, 2018 and August 26, 2022, holders of a total of 6,583,000 shares of our Series A Convertible preferred stock converted their shares to common stock. In addition, in December 2024, the holders of the remaining 5,417,000 shares of our Series A Convertible preferred stock converted their shares into 9,028 shares of our common stock and, as a result of such conversions, no shares of Series A preferred stock remained outstanding at March 31, 2025 or December 31, 2024.

### ***Series B Convertible Preferred Stock***

On November 8, 2017, we issued 6,600,000 shares of convertible preferred stock designated as Series B Convertible preferred stock with an aggregate purchase price and initial liquidation preference of \$3.3 million. Each share of Series B Convertible Preferred Stock was issued for \$0.50 per share. On August 26, 2022, one holder of Series B Convertible preferred stock converted 1,950,000 shares to common stock. In addition, on December 2024, the remaining 4,050,000 shares of Series B Convertible preferred stock were converted into 13,500 shares of our common stock and, as a result of such conversions, no shares of Series B Convertible preferred stock remained outstanding at March 31, 2025 or December 31, 2024.

### ***Series F Convertible Preferred Stock***

In December 2023, we issued 8,000,000 shares of our Series F Convertible preferred stock in connection with our purchase of assets from Odyssey Health, Inc. ("Odyssey") (see Note 9). The Series F Convertible preferred stock is convertible on a one-for-one basis into our common stock to the extent that Odyssey would not hold more than 19.9% of our outstanding common stock following the conversion. Upon issuance, 511,308 shares of Series F Convertible preferred stock were converted to 511,308 shares of our common stock and 7,488,692 shares of Series F Convertible preferred stock remained outstanding at March 31, 2025 and December 31, 2024.

### ***Series G Mirroring Preferred Stock***

In March 2025, in connection with our issuance of a \$3.0 million promissory note (see Note 5), we designated and issued 1,000,000 shares of our authorized but unissued shares of preferred stock as Series G Mirroring preferred stock, no par value and a stated value of \$0.10 per share. On May 2, 2025, upon our shareholders' approval, at our annual shareholders meeting, of a proposal authorizing the Company's Board of Directors, in its discretion at any time within one year after shareholder approval is obtained, to effect a reverse stock split of then-outstanding shares of the Company's common stock, at a ratio of not less than one-for-five (1:5) and not greater than one-for-sixty (1:60), with the exact ratio to be determined by the Company's Board and included in a public announcement (the "Reverse Split Proposal"), in accordance with the Certificate of Designation creating the Series G Mirroring Preferred Stock, all of the shares of Series G Mirroring Preferred Stock were transferred to the Company and cancelled and such shares have resumed the status of authorized but unissued shares of preferred stock and are no longer designated as Series G Preferred Stock.

Following is a summary of the principal terms of the Series G Mirroring Preferred stock:

#### **Dividends**

No dividends shall be paid on shares of the Series G Mirroring preferred stock.

#### **Voting Rights**

The Series G Mirroring preferred stock has no voting rights, except that each share entitles the holder thereof to 1,000 votes per share solely and exclusively with respect to the Reverse Split Proposal, the Amendment Proposal and any Adjournment Proposal (as such terms are defined in the Certificate of Designation creating the Series G Mirroring preferred stock) being voted on at our upcoming Annual Meeting, voting together with our common stock as a single class. The holder agreed to vote all 1,000,000 shares of Series G Mirroring preferred stock on any proposal presented to the shareholders for purposes of approving the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal and has agreed that such shares of Series G Mirroring preferred stock, shall, to the extent voted in favor of such proposals, be automatically and without further action of the holder voted in the same proportions as shares of our common stock are voted on the Reverse Split Proposal, the Amendment Proposal and the Adjournment Proposal, as applicable.

#### **Liquidation**

The Series G Mirroring preferred stock ranked junior to the Series F preferred stock. Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary (a "Liquidation"), the holder was entitled to receive, out of the assets of the Corporation, an amount equal to the Stated Value for each share of Series G Mirroring preferred stock before any distribution or payment could be made to the holders of common stock but after any other class of stock than ranked senior to the Series G Mirroring preferred stock, including the Series F preferred stock.

## Cancellation

Upon the approval of either the Reverse Split Proposal or the Proposal to Increase Authorized Shares, both of which were approved by the Company's shareholders on May 2, 2025, each share of Series G preferred stock was automatically transferred to us and cancelled for no consideration with no action on behalf of the holders of Series G preferred stock, and such shares resumed the status of authorized but unissued preferred stock and no longer are designated as Series G Mirroring preferred stock.

## Preemptive Rights

No holder of Series G Mirroring preferred stock has any preemptive rights to purchase or subscribe for our common stock or any of our other securities.

## Trading Market

There is no established trading market for the Series G Mirroring preferred stock, and we do not expect a market to develop. We do not intend to apply for a listing for the Series G Mirroring preferred stock on any securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the Series G Mirroring preferred stock is limited.

## Note 9. Acquisition of Concussion Assets

On December 28, 2023, we entered into an Asset Purchase Agreement with Odyssey Health, Inc. to purchase their intellectual property assets for their neurology products ONP-001 and ONP-002.

The aggregate purchase price of the transaction was \$10,273,506 as follows:

Cash	\$	1,000,000
Assumed accounts payable		325,672
8,000,000 shares of our Series F Convertible preferred stock		8,947,834
	\$	<u>10,273,506</u>

We evaluated the transaction and determined that it should be accounted for as an asset purchase. Furthermore, it was determined that the assets acquired were in-process research and development and, accordingly, the entire purchase price was recorded as a component of Research and development expense in the fourth quarter of 2023.

## Note 10. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding for the period. Potentially dilutive common stock and common stock equivalents, including stock options and warrants are excluded as they would be antidilutive.

The following anti-dilutive securities were excluded from the calculations of diluted net loss per share:

	Three Months Ended	
	March 31,	
	2025	2024
Stock options	769,888	241,814
Warrants	736,574	298,962
	<u>1,506,462</u>	<u>540,776</u>

## Note 11. Commitments and Contingencies

On December 7, 2022, we 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”). We terminated the Engagement Letter as of August 15, 2023. Ladenburg sent us 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 our purchase of assets from Odyssey Health, Inc. We strongly disagree 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, the District Court Judge adopted the Report and Recommendation, finalizing the Court’s denial of the requested injunctive relief. On May 9, 2024, we filed a motion to dismiss, which is still pending. Meanwhile, the FINRA action continues and is set to be heard in August 2025. We believe Ladenburg’s claims are unlikely to prevail and intend to defend vigorously against such claims. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact our business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that we will prevail. We do not include an estimate of legal fees and other related defense costs in our 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 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, 2024 filed on March 14, 2025.*

### 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 our 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 goals. 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 in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and the other risks and uncertainties described elsewhere in this report as well as other risks identified from time to time in our filings with the Securities and Exchange Commission, press releases and other communications. In addition, the statements contained throughout this Quarterly Report concerning future events or developments or our future activities, including concerning, among other matters, current or planned clinical trials, anticipated research and development activities, anticipated dates for commencement of clinical trials, anticipated completion dates of clinical trials, anticipated meetings with the FDA or other regulatory authorities concerning our product candidates, anticipated dates for submissions to obtain required regulatory marketing approvals, anticipated dates for commercial introduction of products, and other statements concerning our future operations and activities, are forward-looking statements that in each instance assume that we are able to obtain sufficient funding in the near term and thereafter to support such activities and continue our operations and planned activities in a timely manner. There can be no assurance that this will be the case. Also, such statements assume that there are no significant unexpected developments or events that delay or prevent such activities from occurring. Failure to timely obtain sufficient funding, or unexpected developments or events, could delay the occurrence of such events or prevent the events described in any such statements from occurring.

### Overview

We are a development-stage company dedicated to the research and development of nasal delivery pharmaceutical medications in neurology and fighting infectious diseases. Our lead product, ONP-002, is a fully synthetic, non-naturally occurring neurosteroid, is lipophilic, and we believe can cross the blood-brain barrier with the goal of rapidly eliminating swelling, oxidative stress and inflammation while restoring proper blood flow through gene amplification.

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

Our lead product and focus is on the development and commercialization of ONP-002 for the treatment of mild traumatic brain injury (“mTBI” or “Concussion”).

ONP-002, together with our other neurology assets are referred to herein as the Neurology Assets. To date, ONP-002 has been shown to be stable up to 104 degrees for 18 months. The drug candidate is manufactured into a powder and filled into a novel intranasal device. The drug is then administered through the nasal passage from the device. The novel intranasal device is lightweight and easy to use in the field.

We believe the proprietary powder formulation and intranasal administration allows for rapid and direct accessibility to the brain. The device is breath propelled and is designed 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 effectively crosses the blood brain barrier. This mechanism is designed to trap ONP-002 in the nasal cavity allowing for more abundant and faster drug availability in the traumatized brain.

*Expected ONP-002 Product Development Timeline:*

<b>Pre-clinical Animal Studies</b>	<b>Phase 1</b>	<b>Phase 2a</b>	<b>Phase 2b</b>	<b>Phase 3</b>
Complete	Complete	Estimated Q2 2025 start	Estimated Q2 2026 start	Estimated Q2 2027 start

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

### **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.

### **Recent Funding**

#### ***Stock Sale***

In February 2025, we sold 7.8 million shares pursuant to our ATM Agreement with Dawson James for net proceeds of \$2.6 million. See Note 7 of Notes to Consolidated Financial Statements.

#### ***Promissory Note***

In March 2025, we issued a \$3.0 million promissory note at a 17% original issue discount. After expenses, we received net proceeds of \$2.2 million. See Note 5 of Notes to Consolidated Financial Statements.

### **Going Concern**

See Note 1 of Notes to Consolidated Financial Statements.

### **Significant Accounting Policies and Use of Estimates**

During the three months ended March 31, 2025, there were no significant changes to our significant accounting policies and estimates as described in Note 2. *Significant Accounting Policies* included in Part II, Item 8. of our Annual Report on Form 10-K for the year ended December 31, 2024, which was filed with the SEC on March 14, 2025.

## **Future Capital Requirements**

Our capital requirements for 2025 will depend on numerous factors, including the success of our commercialization efforts and of our research and development, the resources we devote to develop and support our technologies and our success in pursuing strategic licensing and funded product development relationships with external partners.

Subject to our ability to raise additional capital including through possible joint ventures and/or partnerships, we expect to incur substantial expenditures to further commercialize or develop our Neurology Assets, 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.

Our plans include seeking both equity and debt financing, alliances or other partnership agreements with entities interested in our technologies, or other business transactions that would generate sufficient resources to ensure continuation of our operations and research and development programs.

Our available cash and cash equivalents of \$3.4 million at March 31, 2025 provide us with limited liquidity. We believe our existing cash and cash equivalents will allow us to fund our operating plan through the third quarter of 2025. 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 would harm our business.

The sale of additional equity or debt securities may result in 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.

Because of the numerous risks and uncertainties associated with research, development, and commercialization 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 Phase II clinical trials for our ONP-002 product candidate, filing an IND with the FDA and, if approved, engaging in Phase III clinical trials;
- identifying and securing clinical sites for the conduct of human trials for our product candidates;
- the number and characteristics of the product candidates we pursue;
- the scope, progress, results, and costs of researching and developing our product candidates, and conducting nonclinical and clinical trials including the research and development expenditures we expect to make in connection with agreements with third parties we put in place to advance our research and development efforts;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- our ability to maintain current research and development licensing agreements and to establish new strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- our ability to achieve our milestones under our ECC agreement and licensing arrangements and the payment obligations we may have;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation; and
- the timing, receipt and amount of sales of, or royalties on, our products and future products, if any.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate.

## **New Accounting Pronouncements**

See Note 2 of Notes to Consolidated Financial Statements.

## Business Segments

We operate in one reportable segment, which includes all activities related to advancing the development of our concussion drug, ONP-002. The determination of a single reportable segment is consistent with the consolidated financial information regularly provided to our chief operating decision maker (CODM). Our CODM is presently our Chief Financial Officer and Interim Chief Executive Officer, who reviews and evaluates consolidated net loss for purposes of assessing performance, making operating decisions, allocating resources and planning and forecasting for future periods. The measure of segment assets is reported on the balance sheet as total assets. During the three-month periods ended March 31, 2025 and 2024 there was no segment revenue.

## Results of Operations

We do not currently sell or market any products and we did not have any revenue in the three-month periods ended March 31, 2025 or 2024.

	<u>Three Months Ended March 31,</u>		<u>Increase (Decrease)</u>	<u>Percentage Change</u>
	<u>2025</u>	<u>2024</u>		
Research and development	\$ 341,542	\$ 663,414	\$ (321,872)	(48.52)%
General and administrative	1,684,685	1,796,689	(112,004)	(6.23)%
Loss from operations	2,026,227	2,460,103	(433,876)	(17.64)%
Other income (expense):				
Interest income	10,203	19,235	(9,032)	(46.96)%
Interest expense	(199,127)	(7,085)	(192,042)	2,710.54%
Foreign currency exchange, net	(1,842)	(2,880)	1,038	(36.04)%
Total other income, net	(190,766)	9,270	(200,036)	(2,157.89)%
Loss before income taxes	2,216,993	2,450,833	(233,840)	(9.54)%
Income tax benefit	-	-	-	0.00%
Net loss	<u>\$ 2,216,993</u>	<u>\$ 2,450,833</u>	<u>\$ (233,840)</u>	<u>(9.54)%</u>

## Research and Development

Research and development consist of expenses incurred in connection with the discovery and development of our product candidates and are divided into clinical research and nonclinical research and development activities.

Clinical research activities consist of clinical trials, manufacturing services and regulatory activities, all of which are largely provided by third parties.

Nonclinical research and development activities consist of our own research activities, research activities provided by third parties, our own nonclinical studies, nonclinical studies provided by third parties and the acquisition of in process research and development.

The decrease in research and development in the three months ended March 31, 2025 compared to the same period of 2024 was due to decreased expense related to our research and development for ONP-002 during the comparable periods.

## General and Administrative

General and administrative expense consists principally of salaries and related costs for personnel in executive, finance, business development, marketing, information technology, legal and human resources functions, facility costs not otherwise included in Research and development expenses, patent filing fees and professional fees for legal, consulting, auditing, and tax services.

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

- to support our research and development activities, which, subject to available capital, we expect to expand as we continue the development of our product candidates, with a focus on ONP-002;
- the efforts we undertake from time to time to raise additional capital; and
- the increased payroll, stock-based compensation, expanded infrastructure and consulting, legal, accounting and investor relations costs associated with being a public company.

The decrease in general and administrative expense was due to the following:

	<u>Three Months Ended March 31, 2025 Compared to Three Months Ended March 31, 2024</u>
<b>Increase (decrease) in:</b>	
Legal and professional fees	\$ 65,588
Salaries and benefits	(271,176)
Insurance	(20,210)
Public company expense	(14,461)
Board compensation	(6,875)
Travel	14,027
Investor relations	126,677
Other	(5,574)
	<u>\$ (112,004)</u>

The increase in legal and professional fees of \$65,588 is the result of a \$143,735 decrease in accounting expense, \$77,260 in legal expense and \$147,640 in consulting expenses offset by an increase in patent related expense in the amount of \$434,222 as compared to the three months ending March 31, 2024. Salaries and benefits decreased due to lower headcount in the three months ending March 31, 2025 compared to the first quarter ending March 31, 2024. Investor relations expense was increased by \$126,677 due to expenses related to our annual shareholder meeting in the three months ending March 31, 2025 as compared to the same period in 2024.





### ***Other Income (Expense)***

Other income (expense) includes local business taxes, interest income, interest expense and realized gains and losses related to foreign currency exchange rates with our vendors. 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 short-term note payable.

The increase in interest expense of \$192,042 for the three months ending March 31, 2025, relates to the amortization of the debt discount and closing costs incurred for the \$3 million debt financing entered into in March 2025.

### **Liquidity and Capital Resources**

See Recent Funding above for a discussion of our recent financings.

Since our inception, we have funded our operations primarily through the sale of equity securities in public and private offerings, debt financing and exercises of stock-based securities. As of March 31, 2025, we had an accumulated deficit of \$219 million and we have yet to achieve profitability. We incurred net losses of \$2.2 million for the three months ended March 31, 2025 and \$10.5 million for the year ended December 31, 2024. We expect to incur significant and increasing operating losses for the foreseeable future as we seek to advance our Neurology Assets through nonclinical testing and clinical trials to ultimately obtain regulatory approval and eventual commercialization.

The following table sets forth our primary sources and uses of cash:

	<b>Three Months Ended March 31,</b>	
	<b>2025</b>	<b>2024</b>
Net cash used in operating activities	\$ (2,112,090)	\$ (3,064,249)
Net cash provided by financing activities	4,668,328	1,652,737
Net decrease in cash and cash equivalents	\$ (2,556,238)	\$ (1,411,512)

### ***Operating Activities***

Cash used in operating activities in both periods resulted from our net loss adjusted for non-cash expenses and changes in operating assets and liabilities.

Significant items affecting net cash used in operating activities in the three months ended March 31, 2025 included a non-cash charge of \$0.2 million of amortization of debt discount and closing costs, a \$0.1 million increase in Prepaid expense and other current assets and a \$0.2 million decrease in Accounts payable and accrued expenses.

Significant items affecting net cash used in operating activities in the three months ended March 31 2024 included a non-cash charge of \$0.1 million for stock-based compensation, a \$0.1 million decrease in Prepaid expenses and other current assets and a \$0.7 million increase in Accounts payable and accrued expenses.

### ***Financing Activities***

Significant financing activities in the three months ended March 31, 2025 included \$2.6 million net proceeds from the issuance of common stock, and \$2.2 million in borrowings on short-term notes payable, offset by \$0.2 million used for payments on our short-term note payable.

Significant financing activities in the three months ended March 31, 2024 included \$1.8 million net proceeds from the issuance of common stock, partially offset by \$0.2 million used for payments on our short-term note payable.

### ***Short-Term Notes Payable***

Our Short-term notes payable consisted of the following:

	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Insurance premium financing of \$636,972 and \$611,109 due in monthly installments of \$67,277 and 54,366 which includes principal and annual interest at 9.55% through May 24, 2025 and May 24, 2024, respectively	\$ 132,963	\$ 328,528
\$3.0 million non-interest bearing promissory note due July 14, 2025	3,000,000	-
	<u>3,132,963</u>	<u>-</u>
Unamortized debt issuance costs and original issue discount	(578,578)	-
	<u>\$ 2,554,385</u>	<u>\$ 328,528</u>

## **Inflation**

Inflation affects the cost of raw materials, goods, and services that we use. Fluctuations in energy costs and commodity prices can affect the cost of raw materials and components. Except with respect to payroll-related costs and costs arising from, or related to, government-imposed regulations, we do not believe that inflation has had a material impact on our results of operations for the periods presented.

## **Off Balance Sheet Arrangements**

We do not have any off balance sheet arrangements.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are a smaller reporting company and are not required to provide information under this item.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2025. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Based on the evaluation of our disclosure controls and procedures as of March 31, 2025, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

### **Changes in Internal Control Over Financial Reporting**

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Limitations on the Effectiveness of Controls**

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our Disclosure Controls and internal controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, 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 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, we 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”). We terminated the Engagement Letter as of August 15, 2023. Ladenburg sent us 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 our purchase of assets from Odyssey Health, Inc. We strongly disagree 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, the District Court Judge adopted the Report and Recommendation, finalizing the Court’s denial of the requested injunctive relief. On May 9, 2024, we filed a motion to dismiss, which is still pending. Meanwhile, the FINRA action continues and is set to be heard in August 2025. We believe Ladenburg’s claims are unlikely to prevail and intend to defend vigorously against such claims. It is possible, however, that there could be an unfavorable outcome or resolution of the claims asserted, which could negatively and materially impact our business, consolidated financial position and results of operations. Litigation is inherently uncertain and there can be no assurance that we will prevail. We do not include an estimate of legal fees and other related defense costs in our estimate of loss contingencies.

### ITEM 1A. RISK FACTORS

There have been no material changes during the three-month period ended March 31, 2025 to the risk factors discussed in our Annual Report on Form 10-K for the year ended December 31, 2024. If any of the identified risks occur, our business, financial condition and results of operations could suffer. The trading price of our common stock could decline and you may lose all or part of your investment in our common stock. The risks and uncertainties described in our Annual Report on Form 10-K for the year ended December 31, 2024 are not the only ones we face. Additional risks that we currently do not know about or that we currently believe to be immaterial may also impair our business operations.

### ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On March 13, 2025, we issued a \$3.0 million promissory note (the “Note”) to a single investor at an original issue discount of 17%. Net proceeds to us were \$2.25 million after placement agent fees of \$175,000 and legal expenses of \$98,437. No interest accrues on the Note unless an event of default occurs, at which time interest will accrue at a rate of 20% per annum. The Note matures upon the earlier of July 14, 2025 or the closing of any subsequent offering by us with net proceeds equal to or in excess of all amounts due under the Note.

In connection with the issuance of the Note, we designated and issued 1,000,000 shares of our authorized but unissued shares of preferred stock as Series G Mirroring preferred stock. For a description of the principal terms of the Series G Mirroring preferred stock, see Note 8.

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

### ITEM 5. OTHER INFORMATION

During the quarter ended March 31, 2025, no director or officer adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408(a) of Regulation S-K.

### ITEM 6. EXHIBITS

The following exhibits are filed herewith and this list constitutes the exhibit index.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>File No.</b>	<b>Exhibit Number</b>	<b>Filing Date</b>	<b>Filed Herewith</b>
3.1	<a href="#"><u>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).</u></a>	8-K	001-32188	3.1	12/29/17	
3.2	<a href="#"><u>Articles of Amendment to Amended and Restated Articles of Incorporation dated effective December 29, 2017.</u></a>	8-K	001-32188	3.2	12/29/17	
3.3	<a href="#"><u>Articles of Amendment to Amended and Restated Articles of Incorporation effective January 19, 2018.</u></a>	8-K	001-32188	3.1	01/19/18	
3.4	<a href="#"><u>Articles of Amendment to Amended and Restated Articles of Incorporation.</u></a>	8-K	001-32188	3.4	06/26/18	
3.5	<a href="#"><u>Articles of Amendment to Amended and Restated Articles of Incorporation.</u></a>	8-K	001-32188	3.5	02/28/22	
3.6	<a href="#"><u>Articles of Amendment to Amended and Restated Articles of Incorporation</u></a>	8-K	001-32188	3.1	01/23/23	
3.7	<a href="#"><u>Amendment to Articles of Incorporation to Increase Common Stock</u></a>	8-K	001-32188	3.1	12/15/23	

3.8	<a href="#">Bylaws</a>	SB-2	333-100568	3.2	10/16/02	
3.9	<a href="#">First Amendment to Bylaws</a>	8-K	001-32188	3.1	06/09/10	
3.10	<a href="#">Second Amendment to Bylaws</a>	8-K	001-32188	3.1	08/24/10	
3.11	<a href="#">Third Amendment to Bylaws</a>	8-K	001-32188	3.9	02/28/22	
10.1	<a href="#">Form of Securities Purchase Agreement</a>	10-K	001-32188	10.25	03/14/2025	
10.2	<a href="#">Form of Note dated March 13, 2025</a>	10-K	001-32188	10.26	03/14/2025	
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934</a>					X
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934</a>					X
32.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 1350</a>					X
32.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 1350</a>					X
101.INS	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted in iXBRL, and included in exhibit 101).					

**SIGNATURE**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, as of May 9, 2025.

**ORAGENICS, INC.**

By: */s/ Janet Huffman*

\_\_\_\_\_  
Janet Huffman

Chief Financial Officer, Secretary, Treasurer, President, Chief Executive Officer  
(Principal Financial and Accounting Officer and Principal Executive Officer)

## CERTIFICATION

I, Janet Huffman, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 (or persons performing the equivalent functions):

(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.

May 9, 2025

*/s/ Janet Huffman*

Janet Huffman

Chief Financial Officer, Chief Executive Officer and President  
(Principal Financial and Accounting Officer and Principal Executive Officer)

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## CERTIFICATION

I, Janet Huffman, certify that:

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

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant 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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 (or persons performing the equivalent functions):

(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.

May 9, 2025

*/s/ Janet Huffman*

Janet Huffman

Chief Financial Officer, Chief Executive Officer and President  
(Principal Financial and Accounting Officer and Principal Executive Officer)

**Certification Pursuant to 18 U.S.C. Section 1350**

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the three months ended March 31, 2025 as filed with the Securities and Exchange Commission (the "SEC") on or about the date hereof (the "Report"), 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

May 9, 2025

*/s/ Janet Huffman*

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Janet Huffman

Chief Financial Officer, Chief Executive Officer and President  
(Principal Financial and Accounting Officer and Principal Executive Officer)

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**Certification Pursuant to 18 U.S.C. Section 1350**

In connection with the Quarterly Report of Oragenics, Inc. (the "Company") on Form 10-Q for the three months ended March 31, 2025 as filed with the Securities and Exchange Commission (the "SEC") on or about the date hereof (the "Report"), 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; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

A signed original of this written statement has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

May 9, 2025

*/s/ Janet Huffman*

Janet Huffman

Chief Financial Officer, Chief Executive Officer and President  
(Principal Financial and Accounting Officer and Principal Executive Officer)

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