ORAGENICS INC

FORM 10-Q
(Quarterly Report)

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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 June 30, 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	**59-3410522**
(State or other jurisdiction of incorporation or organization)	**(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 ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company ☐	

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

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

As of August 7, 2025, there were 4,127,173 shares of common stock, par value $0.001 per share, outstanding.

Note Regarding Reverse Stock Split

On June 3, 2025, the Company effected a 1-for-30 reverse stock split of its outstanding common stock. All share and per share amounts in these consolidated financial statements and related footnotes have been retroactively adjusted to reflect the reverse stock split for all periods presented, unless otherwise indicated (the "Reverse Stock Split").

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

INDEX

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Oragenics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 1,973,745	$ 864,840
Prepaid expenses and other current assets	165,963	607,670
Total current assets	2,139,708	1,472,510
Total assets	$ 2,139,708	$ 1,472,510
Liabilities and Stockholders' Deficit		
Current liabilities:		
Accounts payable and accrued expenses	$ 1,267,423	$ 1,355,867
Short-term notes payable, net of debt issuance costs	3,000,000	328,528
Total liabilities	4,267,423	1,684,395
Stockholders' deficit:		
Preferred stock, no par value; 50,000,000 shares authorized; 7,488,692 and 7,488,692 Series F outstanding at June 30, 2025, and December 31, 2024, respectively	-	-
Common stock, $0.001 par value; 350,000,000 shares authorized; 822,927 and 419,003 shares issued and outstanding at June 30, 2025, and December 31, 2024, respectively	823	419
Additional paid-in capital	219,146,662	216,573,868
Accumulated deficit	(221,275,200)	(216,786,172)
Total stockholders' deficit	(2,127,715)	(211,885)
Total liabilities and stockholders' deficit	$ 2,139,708	$ 1,472,510

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

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 449,679	$ 906,779	$ 791,221	$ 1,570,193
General and administrative	1,264,523	1,399,221	2,949,208	3,195,910
Total operating expenses	1,714,202	2,306,000	3,740,429	4,766,103
Loss from operations	(1,714,202)	(2,306,000)	(3,740,429)	(4,766,103)
Other income (expense):				
Interest income	16,793	6,405	26,996	25,640
Interest expense	(572,310)	(1,803)	(771,437)	(8,888)
Foreign currency exchange net	(2,316)	(3,692)	(4,158)	(6,572)
Total other (expense) income, net	(557,833)	910	(748,599)	10,180
Net loss	$ (2,272,035)	$ (2,305,090)	$ (4,489,028)	$ (4,755,923)
Basic and diluted net loss per share	$ (3.10)	$ (15.27)	$ (6.62)	$ (35.56)
Weight average shares outstanding, basic and diluted	731,817	150,968	677,800	133,752

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

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

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balances at December 31, 2024	419,003	$ 419	7,488,692	$ —	$216,573,868	$(216,786,172)	$ (211,885)
Compensation expense relating to options	—	—	—	—	17,706	—	17,706
Compensation expense recapture relating to options	—	—	—	—	(86,470)	—	(86,470)
Sale of Common Stock	258,849	259	—	—	2,633,931	—	2,634,190
Conversion of prefunded warrants to common stock	37,990	38	—	—	1,102	—	1,140
Issuance of Series G Preferred Stock	—	—	1,000,000	—	—	—	—
Net loss	—	—	—	—	—	(2,216,993)	(2,216,993)
Balances at March 31, 2025	715,843	$ 716	8,488,692	$ —	$219,140,137	$(219,003,165)	$ 137,688
Reverse split fractional shares issued	107,084	107	—	—	(107)	—	—
Compensation expense relating to options	—	—	—	—	6,779	—	6,779
Compensation expense recapture relating to options	—	—	—	—	(147)	—	(147)
Cancellation of Series G Preferred Stock	—	—	(1,000,000)	—	—	—	—
Net loss	—	—	—	—	—	(2,272,035)	(2,272,035)
Balances at June 30, 2025	822,927	$ 823	7,488,692	$ —	$219,146,662	$(221,275,200)	$ (2,127,715)

	Common Stock		Preferred Stock		Additional Paid In Capital	Accumulated Deficit	Total Shareholders' Equity
	Shares	Amount	Shares	Amount			
Balances at December 31, 2023	102,690	$ 103	16,955,197	$1,592,723	$207,793,582	$(206,218,254)	$ 3,168,154
Compensation expense relating to option issuances	—	—	—	—	69,344	—	69,344
Sale of Common Stock	46,667	47	—	—	1,838,554	—	1,838,601
Net loss	—	—	—	—	—	(2,450,833)	(2,450,833)
Balances at March 31, 2024	149,357	$ 150	16,955,197	$1,592,723	$209,701,480	$(208,669,087)	$ 2,625,266
Compensation expense relating to option issuances	—	—	—	—	58,220	—	58,220
Sale of Common Stock	36,667	37	—	—	947,963	—	948,000
Net loss	—	—	—	—	—	(2,305,090)	(2,305,090)
Balances at June 30, 2024	186,024	$ 187	16,955,197	$1,592,723	$210,707,663	$(210,974,177)	$ 1,326,396

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

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

	For the Six Months Ended June 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (4,489,028)	$ (4,755,923)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and closing costs	771,437	-
Stock-based compensation expense	24,485	127,564
Stock-based compensation recapture expense	(86,617)	-
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	441,707	111,939
Operating lease right of use assets	-	9,811
Accounts payable and accrued expenses	(88,444)	(92,358)
Change in operating lease liabilities	-	(9,811)
Net cash used in operating activities	(3,426,460)	(4,608,778)
Cash flows from financing activities:		
Borrowings on short-term notes payable	2,228,563	-
Payments on short-term notes payable	(328,528)	(312,703)
Net proceeds from issuance of common stock	2,635,330	2,786,601
Net cash provided by financing activities	4,535,365	2,473,898
Net decrease in cash and cash equivalents	1,108,905	(2,134,880)
Cash and cash equivalents at beginning of period	864,840	3,483,501
Cash and cash equivalents at end of period	$ 1,973,745	$ 1,348,621
Supplemental disclosure of cash flow information:		
Interest paid	$ 7,860	$ 8,888

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. are 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") applicable to interim financial reporting. All intercompany balances and transactions have been eliminated in consolidation.

In the opinion of management, all adjustments (consisting solely of normal recurring adjustments) considered necessary for a fair presentation of the Companby's consolidated financial position, results of operations, and cash flows for the interim period presented have been included. The condensed consolidated balance sheet as of December 31, 2024, has been derived from the audited financial statements included in the Company's annual report on the Form 10-K for the year ended December 31, 2024, filed with the SEC on March 14, 2025.

These interim financial statements should be read in conjunction with the audited consolidated financial statements and accompanying notes thereto included in the Company's Annual Report on the Form 10-K for the year ended December 31, 2024. The results of operations for the three and six months ended June 30, 2025, are not necessarily indicative of the results that may be expected for the full fiscal year ending December 31, 2025.

On June 3, 2025, the Company effected a 1-for-30 reverse stock split of its outstanding common stock. All share and per share amounts in these consolidated financial statements and related footnotes have been retroactively adjusted to reflect the reverse stock split for all periods presented, unless otherwise indicated.

Significant Accounting Policies

There have been no material changes to the Company's significant accounting policies during the six-month ended June 30, 2025, as compared to those disclosed in the consolidated financial statements included in the Company's Annual Report on the Form 10-K for the year ended December 31, 2024.

Nature of Operations

Organics, Inc. (the "Company") is development-stage biopharmaceutical company dedicated to the research and development of nasally delivered pharmaceutical therapies targeting neurological conditions and infectious diseases. The Company is currently focused on advancing the development and commercialization of its lead product candidate, ONP-002, novel formulation intended for the treatment of mild traumatic brain injury ("mTBI" or "concussion"). ONP-002 is being developed as a potential first-in-class therapeutic targeting the unmet medical need for effective concussion treatment.

Going Concern

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

We have incurred operating losses and negative cash flow from operations since inception. To date, we have not generated significant revenues from our operations. We incurred a net loss of $4.5 million and used $3.4 million cash resources in operating activities during the six months ending June 30, 2025. As of June 30, 2025, we had an accumulated deficit of $221 million and cash and cash equivalents of $2 million.

Historically, our primary sources of liquidity have included proceeds from public and private offerings of our common and preferred stock, warrant exercises, debt financings, grant income, and interest income. During the six months ending June 30, 2025, we raised approximately $2.6 million in net proceeds from private placements and sales of our common stock and received approximately $2.2 million in net proceeds from the issuance of debt.

We expect to continue to incur substantial expenses as we advance the development of ONP-002, our lead product candidate for the treatment of mild traumatic brain injury. Based on our available cash of June 30, 2025, we previously concluded that our working capital would only be sufficient to fund operations through the third quarter of 2025.

Subsequent to quarter-end, on July 2, 2025, we completed a public offering of Series H Preferred Stock and warrants to purchase additional shares of Series H Preferred Stock, resulting in net proceeds of approximately $15.2 million. We believe that this financing meaningfully extends our cash runway and extends our ability to execute on our near-term operating objectives.

While this subsequent financing mitigates some of the liquidity risk, substantial doubt about our ability to continue as a going concern continues to exist unless and until we obtain additional capital to fund operations beyond the current planning horizon. There can be no assurance that we will be able to obtain such financing on acceptable terms, or at all. If we are unable to raise sufficient capital in the future, we may be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts, which would adversely affect our business prospects and ability to continue as a going concern.

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 were $165,963 as of June 30, 2025, compared to $607,670 as of December 31, 2024. The decrease was primarily due to amortization of prepaid insurance and timing of vendor milestone payments related to research and development services.

The Company's prepaid balances typically consist of insurance premiums, research and development service agreements, and other vendor advances aligned with ongoing clinical and regulatory activities.

Note 4. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses totaled $1.3 million as of June 30, 2025, compared to $1.4 million as of December 31, 2024. The decrease was primarily attributable to the timing of vendor payments and lower accrued external R&D and corporate services as of the period end.

These liabilities consist primarily of account payables to research and development partners, payroll and benefits accruals, and other general corporate obligations.

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 approximately $2.2 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 Series G Mirroring Preferred Stock. For a description of the Series G terms, see Note 8. We used the net proceeds for working capital and general corporate purposes. Subsequently, in connection with the Reverse Stock Split the shares of Series G Preferred Stock were cancelled. See Note 8.

Short-term notes payable consisted of the following:

	June 30, 2025	December 31, 2024
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	$ —	$ 328,528
$3.0 million non-interest-bearing promissory note due July 14, 2025	3,000,000	—
	$ 3,000,000	$ 328,528

Subsequent to quarter end, on July 2, 2025, the Company repaid in full the $3.0 million promissory note issued on March 13, 2025. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Stock and warrants to purchase additional shares of Series H Preferred Stock.

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 June 30, 2025, 24,012 shares were reserved for issuance related to the 2021 Plan and 3,142,655 shares of our common stock remain available for awards.

On June 3, 2025, the Company effected a 1-for-30 Reverse Stock Split of its outstanding common shares. However, as approved by shareholders at the Company's 2025 Annual meeting, the total number of authorized shares of common stock for the 2021 Equity Incentive Plan remains unchanged at 3,166,667.

Stock Option Activity

The following table summarizes stock option activity for the six-months ended June 30, 2025. All share amounts have been retroactively adjusted to reflect the Company's 1-for-30 Reverse Stock Split effected on June 3, 2025.

	Number of Shares	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2024	33,150	$ 142.71	6.72	$ —
Cancelled or expired	(9,138)	105.90		
Outstanding at June 30, 2025	24,012	156.72	8.04	—
Exercisable at June 30, 2025	22,844	$ 164.00	7.98	$ —

The cancelled or expired options of 9,138 relate to the forfeiture of stock options.

Unrecognized Stock-Based Compensation Costs

As of June 30, 2025, unrecognized stock-based compensation expense related to unvested stock options was approximately $6,040, which is expected to be recognized over a weighted average period of approximately 0.25 years.

Note 7. Warrants

Outstanding and exercisable warrants as of June 30,2025, are summarized below. All share amounts have been retroactively adjusted to reflect the 1-for-30 Reverse Stock Split effected on June 3, 2025:

Warrants Outstanding	Exercise Price	Expiration Date
1,770	$ 1,800	7/17/2025
2,341	$ 56.25	2/27/2029
1,834	$ 37.50	6/29/2029
13,512	$ 20.70	9/4/2029
19,457		

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 260,000 shares pursuant to the ATM Agreement for net proceeds of $2.6 million after commissions and legal expenses totaling $0.11 million.

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"). The Series F Convertible Preferred Stock is convertible shares of our common stock in accordance with the Certificate of Designation for the Series F Convertible Preferred Stock. Upon issuance, 511,308 shares of Series F Convertible Preferred Stock were converted to 17,044 shares of our common stock. As of June 30, 2025, 7,488,692 shares of Series F Convertible Preferred Stock remain outstanding. Currently, such 7,488,692 shares of Series F preferred stock are convertible into 249,624 shares of our common stock, subject to the provisions and limitations contained in the Certificate of Designation for the Series F Convertible Preferred Stock, which provide that the following Subsequent Conversion Conditions must occur before such shares can be converted: (i) the Company must have applied for and been approved for initial listing on the NYSE American or another national exchange or shall have been delisted from the NYSE American, and (ii) if required by the rules of the NYSE American, the Corporation's shareholder shall have approved any change of control that could be deemed to occur upon the conversion of the Series F Convertible Preferred Stock into Common Stock, based on the facts and circumstances existing at such time.

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 automatically 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.

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 9. Net Loss Per Share

Basic and diluted net loss per share is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Basic and diluted net loss per share are the same for all periods presented, as the inclusion of potentially dilutive securities would have been antidilutive.

All shares and per share amounts have been retroactively adjusted to reflect the Company's 1-for-30 Reverse Stock Split, which became effective on June 3, 2025.

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share because their effect would have been antidilutive:

	Six Months Ended June 30,	
	2025	**2024**
Stock options	24,012	7,431
Warrants	19,457	11,628
	43,469	19,059

Note 10. 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 from September 29 – October 3, 2025. While 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.

Note 11. Subsequent Events

Series H Preferred Stock and Warrants

On May 2, 2025, the Board of Directors of the Company appointed Janet Huffman, the Company's Chief Financial Officer and Interim Chief Executive Officer, to serve as the Company's Chief Executive Officer, in addition to continuing to serve as its Chief Financial Officer, and, in connection therewith, effective May 2, 2025, the Company entered into an Executive Employment Agreement with Ms. Huffman (the "Employment Agreement").

On June 3, 2025, the Company effected a 1-for-30 Reverse Stock Split of its outstanding common stock.

On July 2, 2025, the Company completed a public offering of Series H Convertible Preferred Stock and warrants to purchase additional shares of Series H Convertible Preferred Stock, resulting in gross proceeds of approximately $16.5 million and net proceeds of approximately $15.2 million, after deducting placement agent fees and offering expenses. In connection with the offering, the Company issued 660,000 shares of Series H Preferred Stock, each with a stated value of $25.00, and 660,000 warrants to purchase an equal number of Series H Preferred Shares at an exercise price of $25.00 per warrant. Each share of Series H Preferred Stock is convertible into Common Stock at an initial conversion price of $2.50 per share. The warrants are exercisable immediately and expire on July 2, 2030.

On or about July 2, 2025, the Company repaid in full the $3.0 million promissory note. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Shares and warrants.

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 biopharmaceutical company dedicated to the research and development of nasal delivery pharmaceutical therapies targeting neurological conditions and infectious diseases. The Company is currently focused on advancing the development and commercialization of its lead product candidate, ONP-002. 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 are 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:

Pre-clinical Animal Studies	Phase 1	Phase 2a	Phase 2b	Phase 3
Complete	Complete	Estimated Q3 2025 start	Estimated Q4 2026 start	Estimated Q4 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 260,000 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.

On July 2, 2025, we completed a public offering of 660,000 shares of Series H Convertible Preferred Stock and 660,000 common stock warrants to purchase additional shares of Series H Convertible Preferred Stock, resulting in net proceeds of approximately $15.2 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.

Subsequent to quarter end, on July 2, 2025, the Company repaid in full the $3.0 million promissory note. The repayment was made using a portion of the net proceeds from the Company's July 2, 2025, public offering of Series H Preferred Shares and warrants. 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- and six-months ending June 30, 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 and beyond will depend on numerous factors, including the success of our research and development efforts, the progress of our ONP-002 program, and our ability to secure strategic partnerships or licensing arrangements to support our pipeline.

We expect to incur substantial expenditures to further develop out neurology assets, including increased cost related to research, nonclinical testing, clinical trials, regulatory submissions, and the ongoing requirements of being a public company. Subject to our ability to raise additional capital, we plan to continue advancing the ONP-002 toward Phase II clinical trials and further IND-enabling work.

To support these activities, we may seek additional equity and debt financings, as well as strategic alliances, joint ventures, licensing agreements, or other business arrangements that could generate sufficient capital to sustain our operations.

As of June 30, 2025, we had $1.9 million in cash and cash equivalent. Subsequent to quarter end, on July 2, 2025, we completed a public offering of Series H Convertible Preferred Stock and warrants, resulting in net proceeds of approximately $15.2 million. We believe this capital will allow us to fund our current operating plan through the first half of 2026, depending on the timing and scope of our development activities and other strategic decisions.

Additional capital will still be required to complete planned clinical trials, regulatory filings, and any future commercialization efforts. There can be no assurance that such funding will be available on favorable terms, or at all. If we are unable to secure sufficient capital, we may be forced to delay, scale back, or eliminate certain development programs, which would adversely impact our business and strategic objectives.

The sale of additional equity or convertible securities could result in significant dilution to our existing shareholders. If we raise funds through debt or preferred stock, these instruments may have rights senior to our common stock and could impose restrictive covenants on our operations.

Due to uncertainties associated with clinical development, regulatory approval timelines, and partnership negotiations, we cannot precisely estimate our future capital requirements. However, our needs will depend on many factors, including but not limited to:

- Conducting Phase II trials and filing an IND for ONP-002, including potential Phase III Trial planning;
- Identification and preparation of clinical sites;
- The number and development paths of product candidates we pursue;
- The scope, cost, and results of our preclinical and clinical programs;
- Timing and cost of obtaining regulatory approvals;
- Our ability to secure and maintain strategic partnerships and licensing deals;
- Our performance under existing agreements, including potential milestone or royalty payments;
- Patent prosecution, enforcement, and potential litigation; and
- The timing and revenue, if any, from future product sales and royalties.

We have based these forward-looking statements on assumptions we believe are reasonable; however, actual results and funding needs may differ materially from our current expectations.

New Accounting Pronouncements

See Note 2 of Notes to Consolidated Financial Statements.

Business Segments

We operate in a single reportable segment, which includes all activities related to the development of our lead product candidate, ONP-002, for the treatment of mild traumatic brain injury (concussion). This determination is consistent with how financial information is reviewed and evaluated by our Chief Operation Decision Maker ("CODM") for purposes of performance assessment, resource allocation, and planning.

Our CODM is currently our Chief Executive Officer and Chief Financial Officer, who regularly reviews consolidated net loss and total assets as key measures in operating decision-making. We do not separately evaluate results by geographic region or product line.

For the three and six months ended June 30, 2025, and 2024, we did not generate any revenue. Our segment asset measure is reported on the consolidated balance sheet and total assets.

Results of Operations

We do not currently sell or market any products and did not generate any revenue for the three and six months ended June 30, 2025, and 2024.

	Three Months Ended June 30,		Increase (Decrease)	Percentage Change
	2025	2024		
Research and development	$ 449,679	$ 906,779	$ (457,100)	(50.41)%
General and administrative	1,264,523	1,399,221	(134,698)	(9.63)%
Total operating expenses	1,714,202	2,306,000	(591,798)	(25.66)%
Loss from operations	(1,714,202)	(2,306,000)	(591,798)	(25.66)%
Other income (expense):				
Interest income	16,793	6,405	10,388	162.19%
Interest expense	(572,310)	(1,803)	(570,507)	31,642.10%
Foreign currency exchange, net	(2,316)	(3,692)	1,376	(37.27)%
Total other (expense) income, net	(557,833)	910	(558,743)	(61,400.33)%
Net loss	$ (2,272,035)	$ (2,305,090)	$ 33,055	(1.43)%

	Six Months Ended June 30,		Increase (Decrease)	Percentage Change
	2025	2024		
Research and development	$ 791,221	$ 1,570,193	$ (778,972)	(49.61)%
General and administrative	2,949,208	3,195,910	(246,702)	(7.72)%
Total operating expenses	3,740,429	4,766,103	(1,025,674)	(21.52)%
Loss from operations	(3,740,429)	(4,766,103)	(1,025,674)	(21.52)%
Other income (expense):				
Interest income	26,996	25,640	1,356	5.29%
Interest expense	(771,437)	(8,888)	(762,549)	8,579.53%
Foreign currency exchange, net	(4,158)	(6,572)	2,414	(36.73)%
Total other (expenses) income, net	(748,599)	10,180	(758,779)	(7,453.62)%
Net loss	$ (4,489,028)	$ (4,755,923)	$ 266,895	(5.61)%

Research and Development

For the three months ended June 30, 2025, research and development expenses were $449,679, compared to $906,779 for the same period in 2024, representing a decrease of $457,100 or 50.4%.

For the six months ended June 30, 2025, research and development expenses totaled $791,221, compared to $1.6 million for the same period in 2024, representing a decrease of $778,972 or 49.6%.

In the 2025 periods, the decrease in research and development expenses, was primarily driven by a shift in program activity compared to the prior year. In the 2024 periods, research and development spending included costs related to our vaccine and antibiotics programs, in addition to ONP-002. In contrast, research and development activity in 2025 periods was solely focused on our lead candidate, ONP-002, specifically related to regulatory submissions and approvals required to initiate our Phase IIa clinical trial in Australia and New Zealand. By comparison, ONP-002-related activities in the 2024 periods included formulation work, IND-enabling studies, and broader Phase IIa development efforts.

We anticipate that research and development expenses will increase in future periods as we initiate the Phase IIa trial in Australia, begin IND-enabling work to support a Phase IIb trial in the United States, and commence manufacturing of additional ONP-002 clinical trial material.

General and Administrative

We expect general and administrative expenses to increase in future periods as we:

- Support expanded development of ONP-002 and related pipeline assets;
- Maintain our status as public company, including legal, audit, and compliance costs; and
- Pursue additional capital through equity or strategic transactions.

For the three months ended June 30, 2025, general and administrative expenses were $1.3 million compared to $1.4 million in the same period in 2024, representing a decrease of $134,698, or 9.6%.

For the six months ended June 30, 2025, general and administrative expenses totaled $3.0 million compared to $3.2 million in the prior period, a decrease of $246,702, or 7.7%.

For the quarter, the decrease was primarily driven by a $424,132 decrease in legal and professional fees and a $111,606 decrease in salaries and benefits, attributable to lower external legal support and reduced headcount, respectively. These decreases were partially offset by higher public company expenses of $64,256, reflecting increased audit and regulatory filing costs, and a $45,890 increase in insurance costs due to higher premiums.

On a year-to-date basis, legal and professional fees declined $792,766 due to lower advisory and legal spend compared to the first half of 2024, which included transaction-related activity. Salaries and benefits were also down $382,783. Offsetting these declines were a $754,511 increase in patent expense, which was reclassified from research and development beginning in Q1 2025, as well as a $49,795 increase in public company expenses and $142,897 increase in investor relations driven by annual meeting and shareholder engagement costs.

We expect general and administrative expenses may increase in future periods as we continue to meet our public company compliance obligations, support investor communications, and build operational infrastructure aligned with our development pipeline.

Other Income (Expense)

Other income (expense) includes interest income, interest expense, and realized gains or losses related to foreign currency exchange rates with our vendors. Interest income reflects earnings on our cash and cash equivalents, which are invested with a primary objective of capital preservation. Interest expense consists of costs associated with our short-term note payable, including the amortization of the related debt discount and closing costs.

For the three months ended June 30, 2025, total other expense was $557,833, compared to $910 of income in the prior year period. The change was primarily driven by an increase in interest expense of $570,507, related to the amortization of debt discount and financing costs associated with the $3.0 million note issued in March 2025. The note carries no stated interest unless in default, and the related expense reflects the accounting treatment of the original issue discount and issuance fees.

Liquidity and Capital Resources

See “Recent Funding” above for our discussion of our July 2025 public offering of Series H Preferred Stock and warrants.

Since our inception, we have funded our operations primarily through the sale of equity securities in public and private offerings, debt financing, and the exercise of stock-based awards. As of June 30, 2025, we had an accumulated deficit of $221 million and have not yet achieved profitability. We incurred a net loss of $4.4 million for the six-months ended June 30, 2025, and $10.5 million for the year ended December 31, 2024. We expect to continue incurring significant operating losses as we advance the development of our Neurology Assets, including ONP-002, through regulatory and clinical stages toward potential commercialization.

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

	Six Months Ended June 30,	
	2025	**2024**
Net cash used in operating activities	$ (3,426,460)	$ (4,608,778)
Net cash provided by financing activities	4,535,365	2,473,898
Net increase (decrease) in cash and cash equivalents	$ 1,108,905	$ (2,134,880)

Operating Activities

Cash used in operating activities for the six months ended June 30, 2025, and 2024 was $3.4 million and $4.6 million, respectively. In both periods, cash used in operations resulted primarily from our net losses adjusted for non-cash charges and changes in working capital.

For the six months ending June 30, 2025, significant items affecting cash used in operating activities included a non-cash charge of $771,437 related to amortization of debt discount and an closing costs associated with our March 2025 financing, and stock-based compensation expense of $24,485, partially offset by a stock-based compensation recapture adjustment of $86,617. Changes in operating assets and liabilities also contributed to the net cash outflows, including a $441,707 increase in prepaid expenses and other current assets, and a $88,444 decrease in accounts payable and accrued expense, reflecting timing of payments and reduced research and development activity during the period.

For the six months ended June 30, 2024, non-cash adjustments included $127,564 of stock-based compensation, while working capital changes included a $111,939 increase in prepaid expenses and other current assets, and a $92,358 decrease in accounts payable and accrued expenses.

The reduction in operating cash outflows year-over-year reflects a lower net loss and fewer R&D expenditures during the current period, consistent with our efforts to preserve capital while pursuing additional financing and partnership opportunities.

Financing Activities

Significant financing activities for the six months ended June 30, 2025, included $2.6 million in net proceeds from the issuance of common stock and $2.2 million in borrowing under short-term notes payable, primarily related to the $3.0 million promissory note issued in March 2025. These inflows were partially offset by $328,528 in repayments on short-term notes during the period.

In comparison, financial activities for the six months ended June 30, 2024, included $2.8 million in net proceeds from the issuance of common stock, partially offset by $313,000 in payments on short-term notes payable.

The increase in net financing activity year-over-year reflects the addition of debt financing in 2025, whereas the 2024 period relied solely on equity proceeds to support operations.

Short-Term Notes Payable

On March 13, 2025, the company issued a $3.0 million promissory note (the “Note”) to a single investor at an original issue discount. Net proceeds were approximately $2.2 million, net of placement fees and legal expenses.

The note is non-interest bearing, unless an event of default occurs, in which case interest accrues at a rate of 20% per annum. The note matures upon the earlier of (i) July 14, 2025, or (ii) the closing of any subsequent offering with net proceeds equal to or greater than the outstanding balance.

Subsequent to quarter-end, on July 2, 2025, the Company repaid in full the $3.0 million promissory note. The repayment was made using a portion of the net

proceeds from the Company's July 2, 2025, public offering of Series H Preferred Shares and warrants.

Short-term note payable consisted of the following

	June 30, 2025	December 31, 2024
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	$ -	$ 328,528
$3.0 million non-interest-bearing promissory note due July 14, 2025	3,000,000	-
	$ 3,000,000	$ 328,528

Inflation

Inflation may impact the cost of services and supplies used in our operations, including professional services, insurance premiums, and research-related vendor agreements. Increases in wages, employee benefits, and regulatory compliance costs may continue to exert upward pressure on operating expenses. However, because we are currently in the development stage and do not maintain significant manufacturing operations or large-scale procurement of raw materials, we have not experienced material inflationary effect on our operating results. For the six-month period ending June 30, 2025, and 2024, inflation has not had a material impact on our results of operations.

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 June 30, 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 June 30, 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 from September 29 – October 3, 2025. While 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

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, 2024, 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, 2024, are not the only risks that we face. 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. 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, 2024, filed on March 14, 2025. 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.

The Certificate of Designation for our Series H Convertible Preferred Stock (the "Series H Preferred Stock") contains anti-dilution provisions that may result in the reduction of the Conversion Price for the Series H Preferred Stock in the future. This feature may result in an indeterminate number of shares of Common Stock being issued upon conversion.

The Certificate of Designation for our Series H Preferred Stock contains anti-dilution provisions, which provisions require the lowering of the current $2.50 Conversion Price on any unconverted Series H Preferred Stock to the purchase price of future offerings by us (subject to certain exclusions). If in the future we issue securities for less than the Conversion Price of our Series H Preferred Stock, we will be required to reduce the relevant Conversion Price of any unconverted Series H Preferred Stock, which will result in a greater number of shares of Common Stock being issuable upon conversion, which in turn will have a greater dilutive effect on our shareholders. In addition, as there is no floor price on the Conversion Price, we cannot determine the total number of shares issuable upon conversion. As such, it is possible that we will not have sufficient available shares to satisfy the conversion of the Series H Preferred Stock if we enter into a future transaction that results in the reduction of the Conversion Price. If we do not have sufficient available shares for any Series H Preferred Stock conversions, we will be required to increase our authorized shares, which may not be possible and will be time consuming and expensive. The potential for such Conversion Price adjustments may depress the price of our Common Stock regardless of our business performance, and, as a result, we may find it more difficult to raise additional equity capital while our Series H Preferred Stock is outstanding.

We will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business.

Developing and commercializing biopharmaceutical products, including Phase 2 work for our ONP-002 product candidate and conducting nonclinical studies and clinical trials and establishing manufacturing capabilities, and the progress of our efforts to develop and commercialize our product candidates, is expensive, and can cause us to use our limited, available capital resources faster than we currently anticipate. Our current cash, cash equivalents and short-term investments are not sufficient to fully implement our business strategy and sustain our operations. Our auditor has expressed substantial doubt about our ability to continue as a going concern. We anticipate we will need to raise additional capital in the future to complete the development and commercialization of our product candidates and operate our business. 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. However, our recently completed Series H Preferred Stock offering and the anti-dilution protection contained in the Series H Preferred Stock's Certificate of Designation, as well as our auditor's substantial doubt about our ability to continue as a going concern, may depress the price of our Common Stock regardless of our business performance and may make it more difficult for us to raise or obtain additional financing. Furthermore, even if we are able to obtain additional financing, it may not be on favorable terms and, if such financing is undertaken at a price below the Conversion Price of our Series H Preferred Stock, it will trigger the anti-dilution protection in our Series H Preferred Stock's Certificate of Designation, as discussed above, which in turn may result in a greater number of shares of Common Stock being issued upon conversion of our Series H Preferred Stock, which in turn will have a greater dilutive effect on our shareholders and may make it more difficult to raise additional capital. 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, and, absent sufficient additional financing, we may be unable to remain a going concern.

The market price of our Common Stock may never exceed the Conversion Price of the Series H Preferred Stock.

The warrants we issued in connection with the Series H Preferred Stock offering (the "Series H Warrants") become exercisable upon issuance and will expire five years from the date of issuance. The exercise price of the Series H Warrants is $25 per share of Series H Preferred Stock. Upon exercise, a holder will be required to pay us the exercise price per share in cash and in exchange will receive shares of our Series H Preferred Stock with a stated value of $25. Such shares of Preferred Stock are convertible into shares of Common Stock at the Conversion Price of $2.50. The number of shares of Common Stock into which each share of Preferred Stock is convertible into is determined by dividing the Offering Price by the Conversion Price. Thus, if the Conversion Price is $2.50, each share of Series H Preferred Stock, exclusive of dividends, is convertible into approximately 10 shares of Common Stock. If the market price of our Common Stock is below the Conversion Price, the holder of the Warrant may elect not to exercise the Warrant until the market price of our Common Stock increases. However, the market price of our Common Stock may never exceed the Conversion Price prior to the expiration of the Warrants. As a result, the holders of our Warrants may elect not to ever exercise their Warrants. We will not receive any additional proceeds in connection with unexercised Warrants, which likely will result in our needing to raise additional capital sooner than if some or all of the Warrants are exercised, of which there can be no assurances. Any Warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.

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.

Future sales of our Common Stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our Common Stock, or the perception by the market that those sales could occur, could cause the market price of our Common Stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future. Future issuances of Common Stock could further depress the market for our Common Stock. We expect to continue to incur drug development and selling, general and administrative costs, and to satisfy our funding requirements, we will need to sell additional equity securities, which may include sales of significant amounts of Common Stock to investors, and which Common Stock may be subject to registration rights and warrants with anti-dilutive protective provisions. The sale or the proposed sale of substantial amounts of our Common Stock or other equity securities in the public markets or in private transactions may adversely affect the market price of our Common Stock and our stock price may decline substantially. Our shareholders may experience substantial dilution and a reduction in the price that they are able to obtain upon sale of their shares. Also, new equity securities issued may have greater rights, preferences or privileges than our existing Common Stock. In addition, we have a significant number of shares of restricted stock, stock options and warrants outstanding. The exercise and conversion of such securities will cause additional dilution. Additionally, if we make one or more significant acquisitions in which the consideration includes stock or other securities, our shareholders' holdings may be significantly diluted. In addition, shareholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of Common Stock in lieu of certain cash payments upon the achievement of milestones.

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. Subsequently, in connection with the Reverse Stock Split the shares of Series G Preferred Stock were cancelled. 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 June 30, 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.

Exhibit Number	Exhibit Description	Form	File No.	Exhibit Number	Filing Date	Filed Herewith
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	01/19/18	
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation.	8-K	001-32188	3.4	06/26/18	
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation.	8-K	001-32188	3.5	02/28/22	
3.6	Articles of Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	01/23/23	
3.7	Amendment to Articles of Incorporation to Increase Common Stock	8-K	001-32188	3.1	12/15/23	
3.8	Amendment to Amended and Restated Articles of Incorporation	8-K	001-32188	3.1	05/28/25	
3.9	Certificate of Designation for Series H Preferred Stock	8-K	001-32188	3.1	07/02/25	
3.10	Bylaws	SB-2	333-100568	3.2	10/16/02	
3.11	First Amendment to Bylaws	8-K	001-32188	3.1	06/09/10	
3.12	Second Amendment to Bylaws	8-K	001-32188	3.1	08/24/10	
3.13	Third Amendment to Bylaws	8-K	001-32188	3.9	02/28/22	
4.1	Form of Series H Preferred Warrant.	8-K	001-32188	4.1	07/02/25	
4.2	Warrant Agency Agreement.		001-32188	4.2	07/02/25	
10.1	Form of Securities Purchase Agreement	10-K	001-32188	10.25	03/14/2025	
10.2	Form of Note dated March 13, 2025	10-K	001-32188	10.26	03/14/2025	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934					X
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a) of the Securities Exchange Act of 1934					X
32.1	Certification of Chief Executive Officer pursuant to Section 1350					X
32.2	Certification of Chief Financial Officer pursuant to Section 1350					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 August 8, 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)

Exhibit 31.1

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.

August 8, 2025

/s/ Janet Huffman

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

Exhibit 31.2

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.

August 8, 2025

/s/ Janet Huffman

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

Exhibit 32.1

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 six months ended June 30, 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.

August 8, 2025

/s/ Janet Huffman

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

Exhibit 32.2

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 six months ended June 30, 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.

August 8, 2025

/s/ Janet Huffman

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