

**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, 2024**

or

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

For the transition period from _____ to _____

Commission file number **001-41775**

NEURAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

45-5079684

(I. R. S. Employer
Identification No.)

**11550 N. Meridian Street, Suite 325
Carmel, IN**

(Address of principal executive offices)

46032

(Zip Code)

(812) 689-0791

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock

Trading Symbol(s)
NRXS

Name of each exchange on which registered
NYSE American LLC

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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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.

Large accelerated filer
Non-accelerated filer

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 to Section 7(a)(2)(B) of the Securities Act.

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

The number of shares of the registrant's common stock outstanding as of May 17, 2024 was 6,647,960 shares.

TABLE OF CONTENTS

<u>PART I</u>	3
ITEM 1: <u>FINANCIAL STATEMENTS</u>	3
<u>Condensed Balance Sheets as of March 31, 2024 (Unaudited) and December 31, 2023</u>	3
<u>Condensed Statements of Operations for the Three Months Ended March 31, 2024, and 2023 (Unaudited)</u>	4
<u>Condensed Statements of Stockholders' Deficit for the Three Months Ended March 31, 2024 and 2023 (Unaudited)</u>	5
<u>Condensed Statements of Cash Flows for the Three Months Ended March 31, 2024 and 2023 (Unaudited)</u>	6
<u>Notes to Condensed Financial Statements (Unaudited)</u>	7
ITEM 2: <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATION</u>	24
ITEM 3: <u>QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK</u>	27
ITEM 4: <u>CONTROLS AND PROCEDURES</u>	28
<u>PART II</u>	29
ITEM 1: <u>LEGAL PROCEEDINGS</u>	29
ITEM 1A: <u>RISK FACTORS</u>	29
ITEM 2: <u>UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS</u>	29
ITEM 3: <u>DEFAULTS UPON SENIOR SECURITIES</u>	30
ITEM 5: <u>OTHER INFORMATION</u>	30
ITEM 6: <u>EXHIBITS</u>	31
<u>SIGNATURES</u>	32

PART I

ITEM 1. FINANCIAL STATEMENTS

**NeurAxis, Inc.
Condensed Balance Sheets**

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	\$ 81,752	\$ 78,560
Accounts receivable, net	90,534	73,167
Inventories	20,194	21,220
Prepays and other current assets	215,354	69,663
Total current assets	<u>407,834</u>	<u>242,610</u>
Property and Equipment, at cost:	451,347	436,626
Less - accumulated depreciation	(356,190)	(348,074)
Property and equipment, net	<u>95,157</u>	<u>88,552</u>
Other Assets:		
Operating lease right of use asset, net	337,286	70,263
Intangible assets, net	105,452	108,073
Total Assets	\$ 945,729	\$ 509,498
Liabilities		
Current Liabilities:		
Accounts payable	\$ 1,237,040	\$ 1,204,219
Accrued expenses	816,480	401,088
Current portion of operating lease payable	35,753	49,127
Notes payable	96,456	148,062
Notes payable - convertible notes, net of unamortized financing fees \$235,281 and \$0 as of March 31, 2024 and December 31, 2023, respectively	1,299,719	—
Customer deposits	85,754	74,947
Share liability	227,000	—
Warrant liabilities	17,509	8,225
Total current liabilities	<u>3,815,711</u>	<u>1,885,668</u>
Non-current Liabilities:		
Operating lease payable, net of current portion	314,472	27,071
Total non-current liabilities	<u>314,472</u>	<u>27,071</u>
Total liabilities	<u>4,130,183</u>	<u>1,912,739</u>
Commitments and contingencies (see note 12)		
Stockholders' Deficit		
Convertible Series A Preferred stock, \$0.001 par value; 1,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Convertible Series Seed Preferred stock, \$0.001 par value; 120,000 shares authorized; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value; 100,000,000 shares authorized; 6,594,897 and 6,508,897 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	6,595	6,509
Additional paid in capital	47,487,713	47,148,361
Accumulated deficit	(50,678,762)	(48,558,111)
Total Stockholders' Deficit	<u>(3,184,454)</u>	<u>(1,403,241)</u>
Total Liabilities and Stockholders' Deficit	\$ 945,729	\$ 509,498

Notes to condensed financial statements are an integral part of these statements.

NeurAxis, Inc.
Condensed Statements of Operations (Unaudited)

	For the Three Months Ended March 31,	
	2024	2023
Net Sales	\$ 646,635	\$ 805,110
Cost of Goods Sold	<u>75,081</u>	<u>95,900</u>
Gross Profit	571,554	709,210
Selling Expenses	80,030	107,932
Research and Development	5,570	16,797
General and Administrative	<u>2,318,074</u>	<u>1,480,755</u>
Operating Loss	(1,832,120)	(896,274)
Other Income (Expense):		
Financing charges	(230,824)	(2,772)
Interest expense	(26,560)	(161,689)
Change in fair value of warrant liability	(9,284)	234,807
Change in fair value of derivative liability	—	191,297
Amortization of debt discount and issuance cost	(21,683)	(2,662,655)
Extinguishment of debt liabilities	—	1,129,498
Other income	—	1,550
Other expense	(180)	(7,172)
Total other income (expense), net	<u>(288,531)</u>	<u>(1,277,136)</u>
Net Loss	\$ (2,120,651)	\$ (2,173,410)
Per-Share Data		
Basic and diluted loss per share	\$ (0.32)	\$ (1.18)
Weighted Average Shares Outstanding		
Basic and diluted	<u>6,550,567</u>	<u>2,003,322</u>

Notes to condensed financial statements are an integral part of these statements.

NeurAxis, Inc.

Condensed Statements of Stockholders' Deficit (Unaudited)

	Convertible Series A Preferred Stock		Convertible Series Seed Preferred Stock		Common Stock		Additional Paid In Capital	Accumulated Deficit	Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount			
Balances as of January 1, 2023	506,637	\$ 507	115,477	\$ 115	1,963,322	\$ 1,963	\$ 28,355,230	\$ (33,931,428)	\$ (5,573,613)
Net loss	—	—	—	—	—	—	—	(2,173,410)	(2,173,410)
Balances as of March 31, 2023	506,637	\$ 507	115,477	\$ 115	1,963,322	\$ 1,963	\$ 28,355,230	\$ (36,104,838)	\$ (7,747,023)
Balances as of January 1, 2024	—	\$ —	—	\$ —	6,508,897	\$ 6,509	\$ 47,148,361	\$ (48,558,111)	\$ (1,403,241)
Warrants exercised	—	—	—	—	11,000	11	26,169	—	26,180
Additional paid in capital from warrants issued under consulting agreement	—	—	—	—	—	—	15,543	—	15,543
Additional paid in capital from warrants issued as debt discount	—	—	—	—	—	—	97,465	—	97,465
Common stock issued from agreements	—	—	—	—	75,000	75	200,175	—	200,250
Net loss	—	—	—	—	—	—	—	(2,120,651)	(2,120,651)
Balances as of March 31, 2024	—	\$ —	—	\$ —	6,594,897	\$ 6,595	\$ 47,487,713	\$ (50,678,762)	\$ (3,184,454)

Notes to condensed financial statements are an integral part of these statements.

NeurAxis, Inc.
Condensed Statements of Cash Flows (Unaudited)

	For the Three Months Ended March 31,	
	2024	2023
Cash Flows from Operating Activities		
Net Loss	\$ (2,120,651)	\$ (2,173,410)
Adjustments to reconcile net loss to net cash used by operating activities:		
Amortization of debt discount and issuance cost	21,683	2,662,655
Depreciation and amortization	10,737	9,849
Provisions for losses on accounts receivable	13,634	(3,787)
Non-cash lease expense	17,316	7,780
Stock-based compensation	227,000	—
Extinguishment of derivative liability	—	(1,129,498)
Issuance of common stock for non-cash consideration	50,062	—
Issuance of warrants for non-cash consideration	15,543	—
Finance charges	—	2,772
Change in fair value of derivative liabilities	—	(191,297)
Change in fair value of warrant liabilities	9,284	(234,807)
Changes in operating assets and liabilities:		
Accounts receivable	(31,001)	(185,299)
Inventory	1,026	(28,885)
Prepays and other current assets	4,497	(19,035)
Accounts payable	32,821	468,672
Accrued expenses	415,394	186,829
Customer deposits	10,807	12,898
Operating lease liability	(10,312)	(8,349)
Net cash used by operating activities	<u>(1,332,160)</u>	<u>(622,912)</u>
Cash Flows from Investing Activities		
Additions to property and equipment	(14,722)	(7,608)
Net cash used by investing activities	<u>(14,722)</u>	<u>(7,608)</u>
Cash Flows from Financing Activities		
Offering costs in advance of sale of common stock	—	(78,972)
Proceeds from exercised warrants	26,180	—
Principal payments on notes payable	(51,606)	(2,695,344)
Proceeds from notes payable	—	52,600
Proceeds from convertible notes, net of fees	1,375,500	3,144,000
Net cash provided by financing activities	<u>1,350,074</u>	<u>422,284</u>
Net Increase (Decrease) in Cash and Cash Equivalents	3,192	(208,236)
Cash and Cash Equivalents at Beginning of Period	<u>78,560</u>	<u>253,699</u>
Cash and Cash Equivalents at End of Period	\$ 81,752	\$ 45,463
Supplemental Disclosure of Non-Cash Cash Activities		
Cash paid for interest	\$ 16,889	\$ 35,865
Cash paid for income taxes	—	—
Supplemental Schedule of Non-Cash Investing and Financing Activities		
Recognition of right of use asset	\$ 284,339	\$ —
Common stock issued for consulting services	\$ 200,250	\$ —
Fair value of warrant liabilities from convertible notes	\$ —	\$ 1,541,955
Fair value of derivative liabilities of conversion feature from convertible notes	\$ —	1,532,725
Fair value of warrants from debt discount in convertible notes classified of additional paid in capital	97,465	—

Notes to condensed financial statements are an integral part of these statements.

1. Basis of Presentation, Organization and Other Matters

NeurAxis, Inc. (“we,” “us,” the “Company,” or “NeurAxis”) was established in 2011 and incorporated in the state of Indiana on April 17, 2012, under the name of Innovative Health Solutions, Inc. The name was changed to NeurAxis, Inc. in March of 2022. Additionally, the Company filed a Certificate of Conversion to become a Delaware corporation on June 23, 2022. The authorized shares were increased, and a par value established.

On January 10, 2023, the Company’s board of directors authorized a 1-for-2 reverse stock split. All per share information has been adjusted for this reverse stock split. The reverse split became effective on January 12, 2023. All share and per share amounts for the common stock have been retroactively restated to give effect to the splits.

As part of the conversion to a Delaware corporation, the total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 100,000,000 shares of Common Stock, par value \$0.001 per share (“Common Stock”) and (ii) 1,120,000 shares of Preferred Stock, par value \$0.001 per share (“Preferred Stock”), 1,000,000 of which is hereby designated as “Series A Preferred Stock” and 120,000 of which is hereby designated as “Series Seed Preferred Stock” with the rights, preferences, powers, privileges and restrictions, qualifications and limitations set forth in this Article IV of the Delaware Certificate of Incorporation. All share amounts have been retroactively restated to give effect to these changes.

On August 9, 2023, the Company consummated an initial public offering, conducted on a firm commitment basis, pursuant to which it sold 1,098,667 shares of its common stock at a price of \$6.00 per share, resulting in gross proceeds to the Company of \$6,592,002. Net proceeds to the Company, after deducting underwriting discounts and commissions, 2022 deferred offering costs totaling \$736,736 and offering expenses paid by the Company, were \$4,110,721. All shares sold in our IPO were registered pursuant to a registration statement on Form S-1 (File No. 333- 269179), as amended, declared effective by the SEC on August 9, 2023. Alexander Capital L.P. (“Alexander”) acted as sole book-running manager for the offering and Spartan Capital Securities, LLC acted as co-manager for the offering. The underwriters did not exercise their option to purchase up to an additional 164,801 shares of common stock. The Company paid the underwriters an underwriting discount of seven percent (7%) of the amount raised in the offering. In addition, we also paid the underwriters a non-accountable expense allowance in the amount of 1% (such 8% in commissions and fees amounted to a total of \$527,000) at closing, as well as \$175,000 for the reimbursement of certain of the underwriters’ expenses. Additionally, as partial consideration for services rendered in connection with the offering, the Company issued Alexander unregistered warrants to purchase an aggregate of 65,921 shares of Company common stock, representing 6.0% of the aggregate shares sold in the offering. The warrants have an initial exercise price of \$7.20 per share (equal to 120% of the offering price per share), have a term of five years from the commencement of sales in the offering, and are exercisable at any time.

The Company is headquartered in Carmel, Indiana. The Company specializes in the development, production, and sale of medical neuromodulation devices.

The Company has developed three FDA cleared products, the IB-STIM (DEN180057, 2019), the NSS-2 Bridge (DEN170018, 2017), and the original 510(K) clearance (K140530, 2014).

- The IB-STIM is a percutaneous electrical nerve field stimulator (PENFS) device that is indicated in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome. The IB-STIM currently is the only product marketed and sold by the Company.
- The NSS-2 Bridge is a percutaneous nerve field stimulator (PNFS) device indicated for use in the reduction of the symptoms of opioid withdrawal. The NSS-2 Bridge device was licensed to Masimo Corporation in April 2020, and the Company received a one-time licensing fee of \$250,000 from Masimo. Masimo markets and sells this product as its Masimo Bridge, and the Company will not receive any further licensing payments or other revenue from this product.
- The original 510(K) device was the EAD, an electroacupuncture device, now called NeuroStim. The EAD is no longer being manufactured, sold or distributed but reserved only for research purposes.

The Company’s financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and following the requirements of the U.S. Securities and Exchange Commission (“SEC”) for interim reporting. As permitted under those rules, certain footnotes or other financial information that are normally required by U.S. GAAP can be condensed or omitted. These interim financial statements have been prepared on the same basis as the Company’s annual financial statements and, in the opinion of management, reflect all adjustments which are necessary for a fair presentation of the Company’s financial information. These unaudited interim results are not necessarily indicative of the results to be expected for the year ending December 31, 2024, or any other interim period or for any other future year. These unaudited financial statements should be read in conjunction with the Company’s audited financial statements and the notes thereto for the year ended December 31, 2023.

2. Summary of Significant Accounting Policies

Use of Estimates and Critical Accounting Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements and the reported amounts of revenues and expenses during the reporting periods.

These significant accounting estimates or assumptions bear the risk of change due to the fact that there are uncertainties attached to these estimates or assumptions, and certain estimates or assumptions are difficult to measure or value.

Management bases its estimates on historical experience and on various assumptions that are believed to be reasonable in relation to the financial statements taken as a whole under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources.

Management regularly evaluates the key factors and assumptions used to develop the estimates utilizing currently available information, changes in facts and circumstances, historical experience, and reasonable assumptions. After such evaluations, if deemed appropriate, those estimates are adjusted accordingly. The Company uses estimates in accounting for, among other items, revenue recognition, allowance for credit losses, stock-based compensation, income tax provisions, excess and obsolete inventory reserve, and impairment of property and equipment, and intellectual property. Actual results could differ from those estimates.

Fair Value Measurements

The Company accounts for financial instruments in accordance with ASC 820, Fair Value Measurements and Disclosures (“ASC 820”). ASC 820 establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – Quoted prices (unadjusted) for identical unrestricted assets or liabilities in active markets that the reporting entity has the ability to access as of the measurement date.

Level 2 – Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities: quoted prices in markets that are not active; or financial instruments for which all significant inputs are observable or can be corroborated by observable market data, either directly or indirectly.

Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. These unobservable inputs reflect that reporting entity’s own assumptions about assumptions that market participants would use in pricing the asset or liability. Level 3 assets and liabilities include financial instruments whose value is determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value require significant management judgment or estimation.

The Company’s Level 1 assets/liabilities include cash, accounts receivable, accounts payable, prepaids, and other current assets. Management believes the estimated fair value of these accounts on March 31, 2024 approximate their carrying value as reflected in the balance sheets due to the short-term nature of these instruments or the use of market interest rates for debt instruments.

The Company's Level 3 assets/liabilities include derivative and warrant liabilities. Inputs to determine fair value are generally unobservable and typically reflect management's estimates of assumptions that market participants would use in pricing the asset or liability. The fair values are therefore determined using model-based techniques, including option pricing models and discounted cash flow models. The valuation techniques involve management's estimates and judgment based on unobservable inputs. The fair value estimates may not be indicative of the amounts that would be realized in a market exchange. Additionally, there may be inherent uncertainties or changes in the underlying assumptions used, which could significantly affect the current or future fair value estimates. Unobservable inputs used in the models are significant to the fair values of the assets and liabilities.

There were no transfers between any of the levels during the periods ended March 31, 2024 and December 31, 2023. In addition to assets and liabilities that are recorded at fair value on a recurring basis, the Company's assets and liabilities are also subject to nonrecurring fair value measurements. As of March 31, 2024 and December 31, 2023, the Company had no assets that were measured on a nonrecurring basis.

Basic and Diluted Net Income (Loss) per Share

Earnings or loss per share ("EPS") is computed by dividing net income (loss), net of preferred stock dividends, by the weighted average number of shares of common stock outstanding during the period. Diluted EPS is computed by dividing net income (loss) by the weighted average of all potentially dilutive shares of common stock that were outstanding during the periods presented. As of March 31, 2024 and December 31, 2023, there were no preferred stock dividends declared or paid.

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the period. Diluted net loss per common share is determined using the weighted-average number of common shares outstanding during the period, adjusted for the dilutive effect of common stock equivalents. In periods when losses are reported, which is the case for March 31, 2024 and 2023 presented in these financial statements, the weighted-average number of common shares outstanding excludes common stock equivalents because their inclusion would be anti-dilutive.

The Company had the following potentially dilutive common stock equivalents at March 31, 2024 and 2023:

	<u>2024</u>	<u>2023</u>
Convertible Series A Preferred Stock	—	1,013,270
Convertible Series Seed Preferred Stock	—	230,954
Options	1,319,394	1,319,394
Pre-Funded Warrants for Convertible Series A Preferred Stock	—	289,779
Warrants	1,857,618	954,044
Convertible Bridge Debt	—	717,432
Totals	<u>3,177,012</u>	<u>4,524,873</u>

Revenue Recognition

Neuraxis, Inc. specializes in the development, production, and sale of medical neuromodulation devices to healthcare providers primarily located in the United States. Patented and trademarked neuromodulation devices is the Company's major product line. Products are generally transferred at a point in time (rather than over time). Essentially all the Company's revenue is generated from purchase order contracts.

In accordance with FASB's ASC 606, Revenue from Contracts with Customers, ("ASC 606"), the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services, in an amount that reflects the consideration which the Company expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of ASC 606, it performs the following five steps:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;
- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies a performance obligation.

The Company applies the five-step model to contracts when it determines that it is probable it will collect substantially all the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price, after consideration of variability and constraints, if any, that is allocated to the respective performance obligation when the performance obligation is satisfied.

The Company estimates credit losses on accounts receivable by estimating expected credit losses over the contractual term of the receivable using a discounted cash flow method. When developing this estimate of expected credit losses, the Company considers all available information (past, current, and future) relevant to assessing the collectability of cash flows.

The Company offers a Patient Assistance Program for patients without insurance coverage for IB-Stim. This program extends potential self-pay discounts for IB-Stim devices, based upon household income and size.

Also, the Company offers providers an opt-in program to address adequate insurance claim payments on IB-Stim devices. This program may extend a rebate or invoice credit where the insurance payment and patient responsibility (i.e., deductible, co-payment, and/or co-insurance amounts required by the Payer) are less than the acquisition cost of the IB-Stim device. The Company recognizes revenue at such a time that collection of the amount due is assured.

The following economic factors affect the nature, amount, timing, and uncertainty of the Company's revenue and cash flows as indicated:

Type of customer: Based on dollar amounts of revenue, essentially all of the goods sold by the Company are sold to healthcare customers including hospitals and clinics. Sales to healthcare customers lack seasonality and have a mild correlation with economic cycles.

Geographical location of customers: Sales to customers located within the United States represent essentially all of the Company's sales.

Type of contract: Sales contracts consist of purchase order contracts that tend to be short-term (i.e., less than or equal to one year in duration).

Company's Performance Obligations with Customers:

Timing of Satisfaction

The Company typically satisfies its performance obligations as the goods are delivered.

Goods that are shipped to customers are typically shipped FOB shipping point with freight prepaid by the Company. As such, ownership of goods in transit transfer to the customer when shipped and the customer bears the associated risks (e.g., loss, damage, delay).

Shipping and handling costs are recorded as general and administrative expenses in the Statement of Operations.

Significant Payment Terms

Payment for goods sold by the Company is typically due after an invoice is sent to the customer, within 30 days. However, other payment terms are frequently negotiated with customers ranging from due upon receipt to due within 90 days. Some payment terms may call for payment only after the healthcare provider receives their insurance reimbursement. Invoices for goods are typically sent to customers within three calendar days of shipment. The Company does not offer discounts if the customer pays some or all of an invoiced amount prior to the due date.

None of the Company's contracts have a significant financing component.

Nature

Medical devices that the Company contracts to sell and transfer to customers are manufactured by one specific third-party manufacturer. The manufacturer is located within the state of Indiana. In no case does the Company act as an agent (i.e., the Company does not provide a service of arranging for another party to transfer goods to the customer).

Returns, Refunds, etc.

Orders may not be cancelled after shipment. Customers may return devices within 10 days of delivery if the goods are found to be defective, nonconforming, or otherwise do not meet the stated technical specifications. At the option of the customer, the Company shall either:

- Refund the price paid for any defective or nonconforming products.
- Supply and deliver to the customer replacement conforming products.
- Reimburse the customer for the cost of repairing any defective or nonconforming products.

At the time revenue is recognized, the Company estimates expected returns and excludes those amounts from revenue. The Company also maintains appropriate accounts to reflect the effects of expected returns on the Company's financial position and periodically adjusts those accounts to reflect its actual return experience. Historically, returns have been immaterial, and the Company currently does not provide a provision for this liability.

Going Concern

We have incurred losses since inception and have funded our operations primarily with a combination of sales, debt, and the sale of capital stock. As of March 31, 2024, we had a stockholders' deficit of \$3,184,454 and short-term outstanding borrowings of \$1,396,175. As of March 31, 2024, we had cash of \$81,752 and a working capital deficit of \$3,407,877.

On August 9, 2023, the Company consummated its initial public offering, conducted on a firm commitment basis, pursuant to which it sold 1,098,667 shares of its common stock at a price of \$6.00 per share, resulting in gross proceeds to the Company of \$6,592,002. Net proceeds to the Company, after deducting underwriting discounts and commissions, 2022 deferred offering costs totaling \$736,736 and offering expenses paid by the Company, were \$4,110,721. All shares sold in our IPO were registered pursuant to a registration statement on Form S-1 (File No. 333- 269179), as amended, declared effective by the SEC on August 9, 2023. Alexander Capital L.P. acted as sole book-running manager for the offering and Spartan Capital Securities, LLC acted as co-manager for the offering. The underwriters did not exercise their option to purchase up to an additional 164,801 shares of common stock.

Our future capital requirements will depend upon many factors, including progress with developing, manufacturing, and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes and overall economic conditions in our target markets. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products from customers currently identified in our sales pipeline and to new customers as well. The primary activity that will drive all customers and revenues is the adoption of insurance coverage by commercial insurance carriers nationally, which is a top priority of the Company. These activities, including our planned research and development efforts, will require significant uses of working capital through the rest of 2024 and beyond. Based on our current operating plans, we believe that our existing cash at the time of this filing will only be sufficient to meet our anticipated operating needs through the end of 2024.

Management evaluates whether there are conditions or events that raise substantial doubt about the Company’s ability to continue as a going concern for a period of one year from the date the financial statements are issued.

To date, the Company has experienced operating losses and negative cash flows from operations. Management believes that increased sales and acceptance of their product by insurance providers will allow the Company to achieve profitability in the near term.

While the Company believes in the viability of its strategy to further implement its business plan and generate sufficient revenues and in its ability to raise additional funds by way of a public or private offering of its debt or equity securities, there can be no assurance that it will be able to do so on reasonable terms, or at all. The ability of the Company to continue as a going concern is dependent upon its ability to further implement its business plan and generate sufficient revenues and its ability to raise additional funds by way of a public or private offering. Neither future cash generated from operating activities, nor management’s contingency plans to mitigate the risk and extend cash resources through the evaluation period, are considered probable. As a result, substantial doubt is deemed to exist about the Company’s ability to continue as a going concern. As we continue to incur losses, our transition to profitability is dependent upon achieving a level of revenues adequate to support its cost structure. We may never achieve profitability, and unless and until doing so, we intend to fund future operations through additional dilutive or nondilutive financing. There can be no assurances, however, that additional funding will be available on terms acceptable to us, if at all.

The financial statements do not include any adjustments related to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-19, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which requires the enhancement of income tax disclosures to provide better insight into how an entity’s operations and related tax risks, planning and opportunities affect its tax rate and prospects for future cash flows. The enhanced disclosures require (i) specific categories in a tabular rate reconciliation including both amounts and percentages and (ii) additional information for reconciling items and income tax paid that meet a quantitative threshold. Public business entities are required to adopt the standard for annual periods beginning after December 15, 2024. All other entities are required to adopt the standard for annual periods beginning after December 15, 2025. The adoption of the standard is not expected to have a material impact on the Company’s financial statements.

3. Related Party Transactions

The Company has two demand notes receivable from shareholders related to the sale of common stock on January 1, 2016. Both notes’ initial balances were \$506,400, with interest calculated monthly based on applicable federal rates. No payments have been received on the notes. Since repayment is not assured, the Company provided an allowance for the entire balance of principal and interest as of December 31, 2019. The current allowance is \$1,166,069 as of March 31, 2024. The current loan balances are as follows:

	Loan Receivable	Interest Receivable	Interest Income
March 31, 2024			
Shareholder 1	\$ 506,400	\$ 76,882	\$ 5,944
Shareholder 2	506,400	76,747	5,944
	<u>1,012,800</u>	<u>153,629</u>	<u>11,888</u>
Allowance for Collection Risk	<u>(1,012,800)</u>	<u>(153,629)</u>	<u>(11,888)</u>
Net Balance	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

	Loan Receivable	Interest Receivable	Interest Income
December 31, 2023			
Shareholder 1	\$ 506,400	\$ 70,938	\$ 23,867
Shareholder 2	506,400	70,803	23,867
	1,012,800	141,741	47,734
Allowance for Collection Risk	(1,012,800)	(141,741)	(47,734)
Net Balance	\$ —	\$ —	\$ —

Mr. Bradley Mitch Watkins, Director, provided certain sales, marketing and commercialization consulting services to the Company prior to his appointment to the Board of Directors. For the three months ended March 31, 2024 and 2023, the Company paid Mr. Watkins \$0 and \$564, respectively, for these services. No amounts were owed to Mr. Watkins as of March 31, 2024 and December 31, 2023, respectively, for these services.

The Company's former Chief Financial Officer is contracted for services through a third-party public accounting firm. He is the firm's managing partner and majority shareholder. The firm is engaged by the Company to provide accounting and tax services on a continuous basis. Fees paid for services were \$62,987 and \$17,551 for the three months ended March 31, 2024 and 2023, respectively. The Company owed RBSK for open invoices of \$68,899 and \$84,279 that are included in accounts payable as of March 31, 2024 and December 31, 2023, respectively.

4. Notes Payable

On November 8, 2023, the Company entered into a Securities Purchase Agreement ("SPA") with a shareholder for the issuance 1,260,504 shares of Series B Convertible Preferred Stock, par value \$0.001 per share (the "Series B Preferred Stock"), for an aggregate purchase price of \$3,000,000 paid in 15 monthly installments of \$200,000 each, commencing on the later of January 10, 2024 or a date after stockholders approve of an amendment to the Company's Certificate of Incorporation to authorize the creation of the Series B Preferred Stock (the "Stockholder Approval"). The Series B Preferred Stock is convertible at any time into shares of common stock of the Company without any further consideration. Following the issuance of the Series B Preferred Stock, it will rank senior to the common stock with respect to payments upon the liquidation, dissolution and winding up of the Company. Due to a delay in Stockholder Approval, the Company amended the SPA on February 12, 2024 to issue a promissory note, due and payable on the earlier of 15 months or 12 months if the Series B Preferred Stock has not been authorized before such date, convertible into Series B Preferred Stock with identical funding amounts and terms.

In the first quarter of 2024, the Company entered into a series of convertible promissory notes totaling \$3,135,000 with identical terms to the \$3,000,000 convertible promissory note issued on February 12, 2024 (collectively referred to as the "2024 Convertible Promissory Notes"). As of March 31, 2024, the Company has received \$1,535,000 of the principal amount with the remainder due in monthly installments through the maturity date in March of 2025.

The Company's private placement agent fees included (i) 10% of the funded principal amount and (ii) warrants calculated as 6.0% of the funded principal amount divided by the \$2.38 exercise price. The fair value of the warrants of \$97,465 were deferred as a financing fee and classified as additional paid in capital. The private placement agreement was terminated on March 18, 2014 pursuant to a new advisory agreement (See Note 12).

The 2024 Convertible Promissory Notes bear interest at 8.5% per annum payable quarterly in either cash or common stock at the election of the Company. At any time following the date of shareholder approval to authorize the creation of Series B Preferred Stock prior to the maturity date, the investor may elect to convert all or part of the principal into the Company's Series B Preferred Stock at a conversion price per share equal to \$2.38. Without limiting the foregoing, all principal amounts outstanding on the maturity date will automatically convert into the Company's Series B Preferred Stock. The Series B Preferred Stock is entitled to cumulative dividends at 8.5% per annum (whether or not declared) payable quarterly in either cash or common stock at the \$2.38 conversion price at the election of the Company. Upon conversion to Series B Preferred Stock, the investor may elect, at its option at any time, to convert all or part of the Series B Preferred Stock plus accrued but unpaid dividends into an equivalent amount of common stock at the \$2.38 conversion price. As of March 31, 2024, no investor has converted any portion of the 2024 Convertible Notes into Series B Preferred Stock as the shareholders have not yet authorized its issuance.

Accrued interest totaled \$76,319 and \$66,648 as of March 31, 2024 and December 31, 2023, respectively. The unamortized debt discount on the 2024 Convertible Promissory Notes total \$235,281 as of March 31, 2024. Amortization of the debt discount on the 2024 Convertible Notes totaled \$21,863 for the three months ended March 31, 2024.

5. Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and current and non-current lease liabilities, as applicable.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense, or any incentives received and remeasure the lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date. The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

Assumptions made by the Company at the commencement date are re-evaluated upon occurrence of certain events, including a lease modification. A lease modification results in a separate contract when the modification grants the lessee an additional right of use not included in the original lease and when lease payments increase commensurate with the standalone price for the additional right of use. When a lease modification results in a separate contract, it is accounted for in the same manner as a new lease.

Entities may elect not to separate lease and non-lease components. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all the contract consideration to the lease component only.

The Company's leases are comprised of operating leases for office space. At the inception of the lease, the Company determines whether the lease contract conveys the right to control the use of identified property for a period of time in exchange for consideration. Leases are classified as operating or finance leases at the commencement date of the lease. Operating leases are recorded as operating lease right-of-use assets, other current liabilities, and operating lease liabilities in the Balance Sheets. The Company did not have any finance leases as of March 31, 2024 and December 31, 2023.

The Company had three leases primarily consisting of office space in Versailles and Carmel Indiana. Two of the leases in Versailles started January 1, 2022. Both have an term of one year, with automatic one year renewal, unless 60 day notice of vacating is given, commencing on the execution hereof and continuing through December 31st of each year. The monthly lease payments for these leases are \$470 and \$1,664 with a 4% per annum increase. The new lease in Carmel started January 1, 2024. The initial term is five years and five months. The monthly lease payment started at \$6,721 with an annual increase of 2.5%. As long as the Company isn't in default, they are only obligated to pay an amount equal to 50% of the monthly base rent for months 1-10.

Operating lease right-of-use assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As the implicit interest rate is generally not readily determinable, the Company uses an incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The incremental borrowing rate reflects the estimated rate of interest that the Company would pay to borrow on a collateralized basis over a similar economic environment. Lease expense for the operating lease is recognized on a straight-line basis over the lease term.

Leases may include renewal options, and the renewal option is included in the lease term if the Company concludes that it is reasonably certain that the option will be exercised. Certain leases may contain rent escalation clauses, either fixed or adjusted periodically for inflation of market rates, that are factored into the calculation of lease payments to the extent they are fixed and determinable at lease inception. The Company also has variable lease payments that do not depend on a rate or index, primarily for items such as common area maintenance and real estate taxes, which are recorded as expenses when incurred.

For the three months ended March 31, 2024 and 2023, the Company recognized \$25,756 and \$11,729 of operating lease expense, including short-term lease expense and variable lease costs, which are immaterial.

The following table presents information related to the Company's operating leases:

	March 31, 2024	December 31, 2023
Operating lease right-of-use assets	\$ 337,286	\$ 70,263
Other current liabilities	35,753	49,127
Operating lease liabilities	314,472	27,071
	<u>\$ 350,225</u>	<u>\$ 76,198</u>
Weighted-average remaining lease term (in years)	4.72	3.75
Weighted-average discount rate	15.0%	15.0%

As of March 31, 2024, the maturities of the Company's operating lease liabilities were as follows:

2024	\$ 57,737
2025	111,472
2026	114,702
2027	86,856
2028	89,027
Thereafter	38,025
Total lease payments	<u>497,819</u>
Less: imputed interest	147,594
Total present value of lease payments	<u>\$ 350,225</u>

6. Common Stock and Warrants

The Company authorized 100,000,000 shares of common stock, of which 6,594,897 and 6,508,897 were issued and outstanding as of March 31, 2024 and December 31, 2023, respectively. In conjunction with 1,098,667 common shares issued upon the completion of the initial public offering on August 8, 2023, the Company also issued (i) 1,244,228 common shares upon conversion of 506,637 shares of Convertible Series A Preferred Stock and 115,477 shares of Convertible Series Seed Preferred Stock, (ii) 1,649,900 common shares upon conversion of convertible notes, (iii) 425,000 common shares as payment to vendors for services and (iv) 127,780 common shares upon the exercise of warrants. On January 10, 2023, the Company's board of directors authorized a 2-for-1 reverse stock split. All share information in these financial statements has been adjusted for this reverse stock split.

On January 10, 2023, the Company's board of directors authorized a 2-for-1 reverse stock split. All share information in these financial statements has been adjusted for this reverse stock split.

On August 9, 2023, the Company consummated an initial public offering, conducted on a firm commitment basis, pursuant to which it sold 1,098,667 shares of its common stock at a price of \$6.00 per share, resulting in gross proceeds of \$6,592,002. See Note 1.

On January 2, 2024, the Company issued 75,000 shares of common stock with a fair value of \$200,250 pursuant to a consulting agreement. As the term of the consulting agreement covers the full fiscal year ending December 31, 2024, the Company expensed \$50,062 in the three months ended March 31, 2024 with the remaining \$150,188 recorded in prepaids and other current assets as of March 31, 2024.

In connection with a bridge loan, the Company issued a warrant on September 18, 2018 that allows the holder to purchase common stock from the Company at a share price of \$4.38 per share. The number of shares was based on a formula tied to the final amount of loans made by the holder of \$375,000, multiplied by 150%, and divided by \$70.03. The number of shares based on this formula is 12,852. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. If the fair market value of one share is greater than the warrant price, the holder may elect to receive a number of shares equal to the value of the warrant. If the exercise is in connection with the sale of the Company, the holder may, at its option, condition its exercise of the warrant upon the consummation of such transaction. The warrant expires on September 18, 2028 and can be exercisable either in whole or from time to time in part prior to the expiration date.

The Company issued a second warrant on September 6, 2019, under similar terms but is a penny warrant that allows the holder to purchase 40,000 shares of common stock and is subject to adjustment for certain equity events. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. The warrant expires on September 6, 2029. This warrant was converted to 39,924 shares of common stock on December 28, 2023. The fair market value of the stock on that day was calculated as the average of the daily closing prices per share for the 30 consecutive trading day period ending on the second trading day prior to such date or \$2.61 per share. Since the fair value was greater than the warrant price of \$0.01 per share the holder elected to receive the number of shares equal to 40,000 times the difference between the fair market value and the exercise price divided by the fair market value, resulting in 39,924.

The Company issued a third warrant to Masimo Corporation on April 9, 2020. This warrant was pre-funded in the amount of \$2,734,340. The warrant allows the holder to purchase 289,779 shares of Series A Preferred Stock at \$9.44 per share and is subject to adjustment for certain equity events. The warrant contains certain rights in the event of liquidation, merger, or consolidation of the Company. There will be no additional purchase price for the Warrants. In the event that all outstanding shares of Series A Preferred Stock are converted, automatically or by action of the holders thereof, into Common Stock, including, without limitation, in connection with the Company's initial, underwritten public offering and sale of its Common Stock pursuant to an effective registration statement under the Act, then from and after the date on which all outstanding shares of Series A Preferred Stock have been so converted, this Warrant shall be exercisable for such number of shares of Common Stock into which the Warrant Shares would have been converted had the Warrant Shares been outstanding on the date of such conversion, and the Exercise Price shall equal the Exercise Price in effect as of immediately prior to such conversion divided by the number of shares of Common Stock into which one share of Series A Preferred Stock would have been converted, all subject to further adjustment thereafter from time to time in accordance with the provisions of this Warrant. On August 14, 2023, the 144,890 Series A Preferred Stock warrants were converted to 289,779 common stock warrants.

During 2022, the Company issued 793,655 five-year warrants to purchase common stock equal to one hundred percent (100%) of the shares into which the 2022 convertible notes can be converted at issuance. The 2024 Convertible Promissory Notes triggered the anti-dilution clause of the original agreement and decreased the exercise price to \$2.38.

From March to June of 2023, the Company issued 505,570 one-year warrants to purchase common stock equal to fifty percent (50%) of the shares into which the 2023 convertible notes can be converted at issuance. The warrants have an exercise price of \$5.25 per share. The 2024 Convertible Promissory Notes triggered the anti-dilution clause of the original agreement and decreased the exercise price to \$2.38.

On August 9, 2023, the Company issued 122,202 five-year warrants to purchase common stock pursuant to an advisory agreement with a consulting firm upon closing of the Company's initial public offering. The warrants have an exercise price of \$6.00 per share. The 2024 Convertible Promissory Notes triggered the anti-dilution clause of the original agreement and decreased the exercise price to \$2.38.

On August 14, 2023, the Company issued 186,156 five-year warrants to purchase common stock pursuant to an agreement with an underwriter upon closing of the Company's initial public offering. The warrants have an exercise price of \$7.20 per share. The 2024 Convertible Promissory Notes triggered the anti-dilution clause of the original agreement and decreased the exercise price to \$2.38.

From January to March of 2024, the Company issued 38,697 warrants to its private placement agent in conjunction with the 2024 Convertible Promissory Notes at an exercise price of \$2.38 to purchase common stock.

On March 30, 2024, the Company issued 7,563 warrants pursuant to an advisory agreement at an exercise price of \$2.38 to purchase common stock (See Note 12).

The following is a summary of warrant activity for common stock during the periods ended March 31, 2024 and December 31, 2023:

	Number of Warrants for Common Stock	Weighted-Avg. Exercise Price	Weighted-Avg. Remaining Contractual Life
Outstanding as of January 1, 2023	846,507	\$ 5.06	4.72
Granted	813,928	5.81	4.38
Cancelled/Expired	289,779	0.01	—
Exercised	(127,856)	—	—
Outstanding as of December 31, 2023	1,822,358	\$ 4.69	3.05
Granted	46,260	\$ 2.38	4.94
Converted Prefunded Warrants	—	—	—
Exercised	(11,000)	—	—
Outstanding as of March 31, 2024	1,857,618	\$ 2.05	3.13

The following is a summary of warrant activity for preferred stock during the year ended December 31, 2023:

	Number of Warrants for Preferred Stock	Weighted-Avg. Exercise Price
Outstanding as of January 1, 2023	144,890	\$ 0.01
Granted	—	—
Cancelled/Expired	—	—
Exercised	(144,890)	(0.01)
Outstanding as of December 31, 2023	—	\$ —

There was no preferred stock warrant activity for the three months ended March 31, 2024.

The following table summarizes the Company's warrants outstanding and exercisable as of March 31, 2024.

	Number of Warrants Outstanding	Exercise Price	Expiration Date
Brian Hannasch W-01	12,852	\$ 8.76	September 18, 2028
Masimo Corporation PSA-01	289,779	\$ 0.01	None
2022 Convertible Notes	793,655	\$ 2.38	Various
2023 Convertible Notes	537,949	\$ 2.38	Various
Consulting Agreement Warrants	157,462	\$ 2.38	August 8, 2028
Underwriter's Warrants	65,921	\$ 2.38	August 8, 2028
	1,857,618		

The Company is a party to two investment banking and advisory agreements with a consulting firm engaged in connection with listing our common stock for trading on NYSE. Pursuant to the first advisory agreement, dated March 3, 2022, the Company agreed to pay the consulting firm a monthly consulting fee of \$5,000 and a final payment of \$50,000 upon a successful NYSE listing, and, also upon such listing, to issue the consulting firm shares of our common stock representing 1.5% of our outstanding shares after giving effect to the initial public offering and to issue the consulting firm five-year warrants to purchase shares of our common stock representing 2.0% of our outstanding shares, after giving effect to the initial public offering, on a fully-diluted basis with an exercise price per share representing the public offering price per share. Pursuant to the second advisory agreement with consulting firm, dated June 20, 2022, and amended December 20, 2022, the Company agreed to pay fees in the aggregate of up to \$136,166 for advice in connection with communication and other related matters leading up to, and in connection with, the initial public offering and to issue the consulting firm 125,000 shares of common stock upon a successful NYSE listing. The Company agreed to piggyback registration rights with respect to all shares issued to the consulting firm under both advisory agreements, including shares issuable upon exercise of the warrants. The Company evaluated the agreements and determined that the shares will not be recorded and valued until the performance condition is satisfied.

7. Preferred Stock

The Company has authorized 1,120,000 shares of preferred stock of which 1,000,000 has been designated Series A Preferred Stock and 120,000 has been designated Series Seed Preferred Stock, of which 0 shares of Series A Preferred Stock and 0 shares of Series Seed Preferred Stock are issued and outstanding as of March 31, 2024 and December 31, 2023, respectively.

The following is a summary of Preferred Stock terms:

Voting Rights - The Series A Preferred and Series Seed Preferred shall vote together with the Common Stock on an as-converted basis, and not as separate classes.

Conversion - The Series A Preferred and Series Seed initially convert 1:1 to Common Stock at any time at option of holder, subject to adjustments for stock dividends, splits, combinations, and similar events and as described below under “Anti-dilution Provisions.”

Dividends - The Series A Preferred will carry an annual 8% cumulative dividend, payable upon any liquidation, dissolution or winding up of the Company (the “Accruing Dividend”). For any other dividends or distributions, participation with Common Stock on an as-converted basis.

Liquidation - In the event of any liquidation, dissolution or winding up of the Company, the proceeds shall be paid in the following priority:

First, to the Series A Preferred in proportion to each holder’s respective pro rata Series A Original Purchase Price, plus any pro rata share of the Accruing Dividend until the entire Series A Original Purchase Price and Accruing Dividend are paid;

Second, to the Series Seed Preferred in proportion to each holder’s respective pro rata Series Seed Original Purchase Price until the entire amount of the Series Seed Original Purchase Price is paid; and

Thereafter, the Series A Preferred and Series Seed Preferred participate with the Common Stock pro rata on an as-converted basis.

A merger or consolidation (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) and a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company will be treated as a liquidation event (a “Deemed Liquidation Event”), thereby triggering payment of the liquidation preferences described.

Anti-dilution Provisions - The Series A Preferred have full-ratchet anti-dilution protection so that the conversion price will be reduced to 80% of the price at which any future shares are issued, if less than the Series A Original Purchase Price.

Preferred stock has all converted pursuant to the initial public offering.

8. Stock Options and Awards

The following is a summary of stock option activity for the periods ended March 31, 2024 and December 31, 2023:

	Number of Options	Weighted Avg. Remaining Contractual Life (in years)	Weighted Avg. Exercise Price	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	1,319,394	6.69	\$ 6.94	\$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Cancelled/Expired	—	—	—	—
Exercised	—	—	—	—
Outstanding as of December 31, 2023	1,319,394	5.69	\$ 6.94	\$ —
Granted	—	—	—	—
Forfeited	—	—	—	—
Cancelled/Expired	—	—	—	—
Exercised	—	—	—	—
Outstanding as of March 31, 2024	1,319,394	5.45	\$ 6.94	\$ —
Vested and Exercisable as of March 31, 2024	1,319,394	5.45	\$ 6.94	\$ —

Stock-based compensation expense is classified in the Company's statements of operations as general and administrative expense. Compensation expense totaled \$237,000 and \$0 for the three months ended March 31, 2024 and 2023, respectively (See Note 9). As of March 31, 2024, there was no unrecognized compensation expense related to unvested options granted under the Company's share-based compensation plans.

9. Share Liability

As of March 31, 2024, the Company had not issued 100,000 shares of its common stock pursuant to a hiring grant of an executive officer, representing stock compensation expense of \$237,000 in the three months ended March 31, 2024, due to administrative delays. These shares are classified as share liabilities as they have been authorized but not yet issued as of the reporting date.

The Company expects to issue these shares to the respective shareholder as soon as the administrative delays are resolved. These shares will be recorded as issued and outstanding upon their issuance, and the corresponding share liability will be reclassified to shareholders' equity. The administrative delays are not expected to have any material impact on the financial position or results of operations of the Company.

Management's best estimate is that the administrative delays will be resolved within the next fiscal quarter, at which point the share liabilities will be eliminated, and the shares will be issued. However, the timing of resolution is subject to various factors, and actual timing may vary.

10. Warrant Liabilities

Management evaluates all of the Company's financial instruments and contracts, including issued warrants to purchase its Class A common stock and Series B Preferred Stock, to determine if such instruments are derivatives or contain features that qualify as embedded derivatives, pursuant to ASC 480 and ASC 815-15. The classification of derivative instruments, including whether such instruments should be recorded as liabilities or as equity, is reassessed at the end of each reporting period.

The Company utilizes a Monte Carlo simulation model for warrants that have an option to convert at a variable number of shares to compute the fair value of the derivative and to mark to market the fair value of the derivative at each balance sheet date. The inputs utilized in the application of the Monte Carlo model included a starting stock price, an expected remaining term of each warrant as of the valuation date, estimated volatility, drift, and a risk-free rate. The Company records the change in the fair value of the derivative as other income or expense in the statements of operations.

The Company utilizes a Monte Carlo simulation model for warrants that have an option to convert at a variable number of shares to compute the fair value of the derivative and to mark to market the fair value of the derivative at each balance sheet date. The inputs utilized in the application of the Monte Carlo model included a starting stock price of \$9.20 per share, an expected remaining term of each warrant as of the valuation date, estimated volatility ranging from 68% to 80%, drift, and a risk-free rate ranging from 4.00% to 4.22%.

Risk-free interest rate: The Company uses the risk-free interest rate of a U.S. Treasury Note adjusted to be on a continuous return basis to align with the Black-Scholes option-pricing model.

Dividend yield: The Company uses a 0% expected dividend yield as the Company has not paid dividends to date and does not anticipate declaring dividends in the near future.

Volatility: The Company calculates the expected volatility based on comparable company's historical stock prices with a look back period commensurate with the period to maturity.

Expected term: The Company's remaining term is based on the remaining contractual maturity of the warrants.

The following are the changes in the warrant liabilities during the periods ended March 31, 2024 and December 31, 2023.

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Warrant liabilities as of January 1, 2023	\$ —	\$ —	\$ 2,234,384
Addition	—	—	2,446,502
Changes in fair value of warrant liabilities	—	—	(844,854)
Reclassify to equity	—	—	(3,827,807)
Warrant liabilities as of December 31, 2023	—	—	8,225
Changes in fair value of warrant liabilities	—	—	9,284
Warrant liabilities as of March 31, 2024	\$ —	\$ —	\$ 17,509

11. Derivative Liabilities

The Company accounts for derivative financial instruments as either equity or liabilities in accordance with ASC Topic 815, *Derivatives and Hedging*, or ASC 815, based on the characteristics and provisions of each instrument. Embedded derivatives are required to be bifurcated from the host instruments and recorded at fair value if the derivatives are not clearly and closely related to the host instruments on the date of issuance. Derivative instrument liabilities are classified in the balance sheets as current or non-current based on whether or not net-cash settlement of the derivative instrument could be required within 12 months of the balance sheet date.

The Company has identified derivative instruments arising from the conversion shares from convertible notes in Note 4 as of March 31, 2024 and December 31, 2023.

The Company utilizes a Monte Carlo simulation model for commitment shares that have an option to convert at a variable number of shares to compute the fair value of the derivative and to mark to market the fair value of the derivative at each balance sheet date. The inputs utilized in the application of the Monte Carlo model included a starting stock price of \$9.20 per share, an expected remaining term of each warrant as of the valuation date, estimated volatility of 80%, drift, and a risk-free rate ranging from 3.46% to 5.47%.

Risk-free interest rate: The Company uses the risk-free interest rate of a U.S. Treasury Note adjusted to be on a continuous return basis to align with the Black-Scholes option-pricing model.

Dividend yield: The Company uses a 0% expected dividend yield as the Company has not paid dividends to date and does not anticipate declaring dividends in the near future.

Volatility: The Company calculates the expected volatility based on comparable company's historical stock prices with a look back period commensurate with the period to maturity.

Expected term: The Company's remaining term is based on the remaining contractual maturity of the warrants.

The following are the changes in the derivative liabilities during the year ended December 31, 2023.

	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>
Derivative liabilities as of January 1, 2023	\$ —	\$ —	\$ 1,735,700
Addition	—	—	2,375,378
Changes in fair value of derivative liabilities	—	—	(198,551)
Extinguishment of derivative liabilities	—	—	(3,912,527)
Derivative liabilities as of December 31, 2023	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

There was no derivative liability activity for the three months ended March 31, 2024.

12. Commitments and Contingencies

Manufacturing Services Agreement

On August 21, 2020, the Company entered into a Manufacturing Services Agreement (MSA) for the manufacture and supply of the Company's IB-STIM device based upon the Company's product specifications as set forth in the MSA. This agreement terminated any prior manufacturing agreements.

The Company provides the necessary equipment to the manufacturer and retains ownership. The manufacturer bears the risk of loss of and damage to the equipment and consigned materials. Performance under the MSA is initiated by orders issued by the Company and accepted by the manufacturer.

The term of the MSA is 24 months and shall automatically renew for renewal terms of twelve months unless either party provides a written termination notice to the other party within 180 days prior to the end of the then-current term.

Trademark Agreement

The Company entered into an agreement for a trademark related to the Company's name on July 11, 2022. The agreement called for an initial payment of \$10,000 upon execution of the agreement. A second and final payment of \$40,000 was contingent upon the completion of the Company's planned initial public offering. The second payment has been accrued and is recorded in accounts payable and intangible assets on the balance sheet. The trademark does not have a determinate life and therefore the cost is not being amortized.

Advisory Agreement

On March 18, 2024, the Company terminated its private placement services agreement and entered into an advisory agreement for debt, equity and public securities market services for one year. The advisory agreement includes a monthly fee of \$30,000 and 7,563 common stock warrants to be issued monthly at an exercise price of \$2.38 with a term of five years.

Executive Employment Agreements

The Company, as authorized by the board of directors, entered into employment agreements with nine key employees to provide incentives to improve shareholder value and to contribute to the growth and financial success of the Company. The agreements had an employment start date of October 1, 2022, with initial terms from 2 to 5 years and optional one-year renewals.

The total base salaries for the nine key employees in the agreements are \$1,920,000 per year with various provisions for annual increases. In addition to base salaries, eight of the employees have a provision for a special one-time incentive payment to be paid in a lump sum after the start date. The total amount of these special incentive payments is \$1,100,000. The special incentive payment amount includes any accrued backpay wages for the employee. That amount for backpay was \$417,390 and was paid in 2023.

There are seven key employees that have stock options of the Company totaling 1,238,712 shares. These key employees have a provision in their agreements whereas the Company will pay a special bonus equal to the aggregate of the strike price or exercise price of all their stock options plus a tax gross-up payment. The special bonus shall be paid in twenty percent (20%) installments starting January 2, 2024, and the same date each of the next four years. As a condition of the payment, the key employee must exercise at least 20% of their stated number of stock options. There are additional provisions to cover termination and change of control events.

In April 2023, the Company amended the employee agreements to, among other things, clarify that the special one-time incentive payment and the deferred bonus are contingent upon the effective date of the planned initial public offering. The amendment also sets forth a process for executives to exercise the stock options in accordance with the terms of the stock option agreement in effect as of the date of the employment agreement and to clarify that there is no modification to the stock option agreements.

The Company has recorded the backpay portion of the incentive bonus noted above. The balance of the incentive bonuses of \$694,056 and the special options bonuses of \$14,821,830 were contingent upon a successful initial public offering. The incentive bonuses have been paid in full while the special options bonuses will be recorded when paid.

Litigation

From time to time in the normal course of our business operations, we may become subject to litigation that may result in liability material to our financial condition as a whole or may negatively affect our operating results if changes to our business operations are required. The cost to defend such litigation may be significant and may require a significant diversion of our resources, and there is no guarantee that we will be able to successfully defend against any such litigation regardless of particular merits. There also may be adverse publicity associated with litigation that could negatively affect customer perception of our business, regardless of whether the allegations are valid or whether we are ultimately found liable. Insurance may not be available on favorable terms, at all, or in sufficient amounts to cover any liabilities with respect to these or other matters. A judgment or other liability in excess of our insurance coverage for any claims could adversely affect our business, financial condition and the results of our operations.

On February 6, 2019, plaintiff Ritu Bhambhani, M.D., initiated a lawsuit against Innovative Health Solutions, Inc. and others in the United States District Court for the District of Maryland. Plaintiffs Bhambhani and Sudhir Rao subsequently amended the complaint, with the Third Amended Complaint (“Complaint”) containing the most recent set of allegations. The Complaint asserted claims under the RICO Act, as well as of fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and sought compensatory damages in excess of \$5 million, pre-judgment interest, punitive damages, attorney’s fees, court costs and designation of the case as a class action. The Complaint states that the Company, distributors of the Company’s product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company’s NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On February 11, 2022, the Company filed a motion for summary judgment based upon the plaintiffs not being proper parties to assert claims against the Company. On June 14, 2022, the Court granted the Company's motion for summary judgment and dismissed the Complaint.

On July 14, 2022, plaintiffs Ritu Bhambhani and Sudhir Rao filed a notice of appeal with the Fourth Circuit Court of Appeals. The Company filed a motion to dismiss. On January 4, 2023, the Court issued an order that stated it was deferring a ruling on the motion to dismiss the appeal and that it would address those arguments at the same time that it addressed the substantive merits of the case. As of May 5, 2023, the parties have submitted their appellate briefs to the Fourth Circuit. No date has been set for either oral argument or for issuance of a decision by the court. While it is too early to predict the ultimate outcome of this matter, we continue to believe we have meritorious defenses, that the dismissal of the Complaint should be upheld, and intend to continue to defend this matter vigorously.

On July 14, 2022, plaintiffs Ritu Bhambhani, LLC; Box Hill Surgery Center, LLC; Pain and Spine Specialists of Maryland, LLC; and SimCare ASC, LLC initiated a lawsuit against the Company and others in the United States District Court for the District of Maryland. The plaintiffs in this lawsuit are business entities owned or partially owned by the plaintiffs that initiated the litigation described above. The Complaint asserted claims under the RICO Act, as well as fraudulent misrepresentation, intentional misrepresentation by concealment, and civil conspiracy and seeks compensatory damages in excess of \$75,000, pre-judgment interest, punitive damages, attorney's fees, and court costs. The Complaint states that the Company, distributors of the Company's product, and medical billing and coding consultants allegedly made misrepresentations to the plaintiffs that the Company's NeuroStim device and related procedures could be billed to, and reimbursed by, Medicare and other insurance payors as a surgically implantable neurostimulator. Plaintiffs claim to have suffered damages when Medicare administrative contractors declined to pay plaintiffs for their use of the device.

On September 28, 2022, the Company filed a motion to dismiss all claims. On May 25, 2023, the Court issued an Order and a Memorandum Opinion which dismissed the plaintiff's claims related to the RICO Act. The remaining claims are still pending, and no trial date has been set for the case.

The Court has vacated its Scheduling Order at the parties' request so that the parties could try to resolve the disputes in both cases through an independent third-party mediator. No mediation date has been set. While it is too early to predict the ultimate outcome of this matter, we believe the Company has meritorious defenses and intends to defend this matter vigorously.

13. Subsequent Events

On April 4, 2024, the Board approved the issuance of 53,063 shares of common stock to an existing shareholder to settle a 2023 convertible note dispute. As the condition existed as of March 31, 2024, the Company expensed the settlement value of \$230,823 to financing charges for the three months ended March 31, 2024.

On April 10, 2024, the employment of the Company's Chief Operating Officer was terminated. Pursuant to the employment agreement, the Company will make salary continuation payments based on an annual salary of \$275,000 through October 10, 2024 and provide health care coverage through October 10, 2025.

ITEM 2: MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial statements and the related notes appearing in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks, uncertainties, and assumptions. You should read the “Cautionary Note Regarding Forward-Looking Statements” and “Risk Factors” sections of our final prospectus filed with the United States Securities and Exchange Commission (the “SEC”) on August 11, 2023 pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the “Prospectus”) (filed in connection with our IPO) for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a growth stage company focused on developing neuromodulation therapies to address chronic and debilitating conditions in children. Our mission is to provide solutions that create value and provide better and safer patient outcomes. Our IB-Stim device is a PENFS system intended to be used in patients 11-18 years of age with functional abdominal pain associated with IBS. Our device already has market clearance from FDA for functional abdominal pain associated with IBS in children. Other indications in our pipeline are comprised of functional nausea in children, post-concussion syndrome in children, and cyclic vomiting syndrome in children. For more information, see “*Business—Our Pipeline*” and “*—Products.*”

Since our inception, we have incurred significant operating losses. Our net loss was \$2,120,651 and \$2,173,410 for the three months ended March 31, 2024 and 2023, respectively. Our auditors have expressed substantial doubt about our ability to continue as a going concern in their audit opinion. We expect to incur significant expenses and operating losses for the foreseeable future as we continue to pursue widespread insurance coverage of our IB-Stim device and seek FDA clearance of our device for other indications. There are a number of milestones and conditions that we must satisfy before we will be able to generate sufficient revenue to fund our operations, including FDA clearance of our IB-Stim device to treat future indications.

Factors Affecting our Business and Results of Operations

Revenue

Our revenue is derived from the sale of our IB-Stim device to healthcare companies, primarily hospitals and clinics. Sales generally are not seasonal and only mildly correlated with economic cycles. Our IB-Stim device sells for \$1,195 per device, and each child being treated for functional abdominal pain associated with IBS will use three to four devices. Potential patients with future indications are expected to use six or more devices per patient.

Our sales typically are made on a purchase order basis rather than through long-term purchase commitments. We enter into sales agreements with customers for IB-Stim devices based on purchase orders and standard terms, which vary slightly based on the customer’s form, and conditions of sale. Standard payment terms generally are that payment is due within 30 days.

Inflation did not have a material impact on our operations for any applicable period, and we do not expect inflation to have a material impact on our operations for the foreseeable future.

Gross Profit and Gross Margin

Our management uses gross profit and gross margin to evaluate the efficiency of operations and as a key component to determining the effectiveness and allocation of resources. We calculate gross profit as revenue less cost of goods sold, and gross margin as gross profit divided by revenue. Our gross margin has been and will continue to be affected by a variety of factors, primarily the average selling price of our IB-Stim device, production volume, order flows, change in mix of customers, third-party manufacturing costs related to components of our IB-Stim device, and cost-reduction strategies. We expect our gross profit to increase for the foreseeable future as our revenue grows, both through broader insurer acceptance of our IB-Stim device in the near term and approval of our technology for the treatment of other indications over the longer term. Our gross margin may fluctuate from quarter to quarter due to changes in average selling prices, particularly as we introduce enhancements to our IB-Stim device and new products to address other indications, and as we adopt new manufacturing processes and technologies.

Expenses

We have four categories of expenses: cost of goods sold, selling expenses, research and development, and general and administrative.

Costs of goods sold consist of costs paid for the IB-Stim device to our contract manufacturer along with periodic inventory adjustments and expired inventory write-offs. Expired inventory expense is related to our FDA clearance for our device in the treatment of functional abdominal pain associated with IBS in children. Specifically, a certain component of our IB-Stim device is cleared for a two-year period after the date the device is manufactured, and if the device is not sold in such period, we must take the device out of inventory and write it off. We had no expired inventory for the three months ended March 31, 2024 and 2023. Expired inventory has not been material to our results, averaging 1% or less of revenue over the last four years. We have a fixed-price contract with the manufacturer of our IB-Stim device to produce the device. We expect production costs to remain relatively constant and only nominal inventory expirations in the foreseeable future.

Our core selling expenses primarily consist of commissions and shipping costs. These expense items are generally correlated with sales.

Research and development expense is attributable to our clinical trials and related efforts to have our IB-Stim device cleared by the FDA for other indications. We expect to incur future R&D expenses for other indications, such as functional nausea, post-concussion syndrome and cyclic vomiting syndrome in children.

General and administrative expense primarily consists of wages and benefits, professional fees including legal and audit, insurance, investor relations, advertising, facility costs, utilities and travel.

Results of Operations

The following table presents our statements of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Net sales	\$ 646,635	\$ 805,110
Cost of goods sold	75,081	95,900
Gross profit	571,554	709,210
Selling expenses	80,030	107,932
Research and development	5,570	16,797
General and administrative	2,318,074	1,480,755
Operating loss	(1,832,120)	(896,274)
Other (expense) income, net:		
Financing charges	(230,824)	(2,772)
Interest expense	(26,560)	(161,689)
Change in fair value of warrant liability	(9,284)	234,807
Change in fair value of derivative financial instruments	-	191,297
Amortization of debt discount and issuance cost	(21,683)	(2,662,655)
Extinguishment of debt liabilities	-	1,129,498
Other expense, net	(180)	(5,622)
Total other (expense) income, net	(288,531)	(1,277,136)
Net loss	\$ (2,120,651)	\$ (2,173,410)

Net Sales

Net sales declined \$158,475, or 19.7%, to \$646,635 for the three months ended March 31, 2024 due to (i) management's focus on gaining further insurance coverage for our products and capital funding and (ii) fewer shipments to certain customers as they transition to the insurance reimbursement process which requires alignment with physician protocols, billing and coding, partially offset by growth in our patient assistance program that provides discounts to patients without insurance coverage.

Gross Profit and Gross Margin

Gross profit declined \$137,656, or 19.4%, to \$571,554 for the three months ended March 31, 2024 due to lower sales volume, partially offset by an increase in our gross margin of 30 bps to 88.4% for the three months ended March 31, 2024 from 88.1% for the three months ended March 31, 2023, due to growth in our patient assistance program at lower discounts to patients without insurance coverage.

Selling Expenses

Selling expenses declined \$27,902, or 25.9%, to \$80,030 for the three months ended March 31, 2024 due to lower sales volume.

Research and Development

Research and development expense declined \$11,227, or 66.8%, to \$5,570 for the three months ended March 31, 2024 due to more patient trials conducted in the three months ended March 31, 2023 as the Company prepared for more FDA submissions.

General and Administrative

General and administrative expense increased \$837,319, or 56.5%, to \$2,318,074 for the three months ended March 31, 2024 due to (i) incremental headcount to build out the market access, sales and finance teams including recruiting costs, (ii) higher legal, insurance, investor relations and board of director costs as a publicly-held entity that the Company did not incur previously, (iii) one-time non-cash advisory costs of \$50,000, (iv) one-time non-cash stock compensation charges of \$237,000 for a hiring grant of stock and (v) higher advertising costs in order to expand market awareness.

Operating Loss

Our operating loss increased \$935,846, or 104.4%, to \$1,832,120 for the three months ended March 31, 2024 primarily due to lower sales volume and higher general and administrative expenses including \$287,000 of one-time non-cash charges.

Other (Expense) Income

Other expense decreased \$988,605, or 77.4%, to \$288,531 for the three months ended March 31, 2024 primarily due to (i) the full conversion of the convertible notes upon the IPO on August 9, 2023 that eliminated any further debt discount, issuance cost, debt extinguishment and derivative fair valuation net charges and (ii) lower interest expense and issuance cost amortization from a lower debt burden, partly offset by finance charges incurred to settle a 2023 convertible note dispute.

Net Loss

Our net loss improved \$52,759, or 2.4%, to \$2,120,651 for the three months ended March 31, 2024 primarily due to the elimination of debt discount, issuance cost, debt extinguishment and derivative fair valuation net charges due to conversion of the convertible notes upon the IPO on August 9, 2023, partly offset by lower sales volume, higher general and administrative expenses (inclusive of \$287,000 of one-time non-cash charges) and the settlement of a 2023 convertible note dispute.

Liquidity and Capital Resources

We had cash on hand of \$81,752 and \$45,463 as March 31, 2024 and 2023, respectively. We maintained a working capital deficit of \$3,407,877 and \$8,755,744 as of March 31, 2024 and 2023, respectively. The increase in working capital was primarily due to (i) the conversion of notes payable upon the IPO on August 9, 2023 along with the corresponding elimination or reduction of the fair value liability of warrants and derivatives and (ii) payments of employee bonuses and vendors with proceeds from the IPO.

We have incurred losses since inception and have funded our operations primarily with a combination of sales, debt, and the sale of capital stock. As of March 31, 2024, we had a stockholders' deficit of \$3,184,454 and short-term borrowings of \$1,396,175.

Our future capital requirements will depend upon many factors, including progress with developing, manufacturing, and marketing our technologies, the time and costs involved in preparing, filing, prosecuting, maintaining, and enforcing patent claims and other proprietary rights, our ability to establish collaborative arrangements, marketing activities and competing technological and market developments, including regulatory changes and overall economic conditions in our target markets. Our ability to generate revenue and achieve profitability requires us to successfully market and secure purchase orders for our products from customers currently identified in our sales pipeline and to new customers as well. The primary activity that will drive all customers and revenues is the adoption of insurance coverage by commercial insurance carriers nationally, so this is a top priority of the Company. These activities, including our planned research and development efforts, will require significant uses of working capital through the rest of 2024 and beyond. Based on our current operating plans, we believe that our existing cash at the time of this filing will only be sufficient to meet our anticipated operating needs through the end of 2024.

Additionally, we will have to meet all the financial disclosure and reporting requirements associated with being a publicly reporting company. Our management will have to spend additional time on policies and procedures to make sure it is compliant with various regulatory requirements, especially that of Section 404 of the Sarbanes-Oxley Act. This additional corporate governance time required of management could limit the amount of time our management has to implement our business plan and may delay our anticipated growth plans.

The following table summarizes our cash flow from operating, investing and financing activities for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Net cash used in operating activities	\$ (1,332,160)	\$ (622,912)
Net cash used in investing activities	(14,722)	(7,608)
Net cash provided by financing activities	1,350,074	422,284
Net decrease in cash and cash equivalents	3,192	(208,236)
Cash and cash equivalents at beginning of period	78,560	253,699
Cash and cash equivalents at end of period	\$ 81,752	\$ 45,463

Operating Activities – Net cash used in operating activities decreased \$709,248, or 113.9% for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to lower sales volume, higher general and administrative expenses and payment of past due vendors.

Investing Activities – Net cash used in investing activities increased \$7,114, or 93.5%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 due to purchases of equipment.

Financing Activities – Net cash provided by financing activities increased \$927,790, or 219.7%, for the three months ended March 31, 2024 compared to the three months ended March 31, 2023 primarily due to proceeds from the issuance of convertible notes whereas the proceeds from convertible notes issued during the three months ended March 31, 2023 were used to repay previously issued notes payable.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Application of U.S. GAAP and Disclosure Controls and Procedures

Our management has evaluated, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our (i) controls over the application of U.S. GAAP based on guidance and interpretations issued by the Financial Accounting Standards Board through the Accounting Standards Codification and Accounting Standards Updates and (ii) disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of March 31, 2024, our U.S. GAAP reporting and disclosure controls and procedures were not effective in ensuring that information required to be reported under U.S. GAAP and disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is (i) recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC and (ii) accumulated and communicated to our management, including our principal executive and principal accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Due to accounting resource constraints, we have had limited review controls. These constraints have resulted in (i) a lack of segregation of duties since we have a limited administrative staff, (ii) a lack of internal controls structure review and (iii) a restatement of our unaudited financial statements as of and for the three and nine month periods ended September 30, 2023. As a result of these constraints, we had material weaknesses in our internal control over financing reporting as of March 31, 2024.

The Company's assessment identified certain material weaknesses which are set forth below:

Functional Controls and Segregation of Duties

Because of the Company's limited resources, there are limited controls over information processing. Additionally, there is inadequate segregation of duties consistent with control objectives. Our management is composed of a small number of individuals resulting in a situation where limitations on segregation of duties exist. All responsibility for accounting entries and the creation of financial statements is held by a single person, though the Company engages multiple accounting consultants for accounting, tax and audit support. To remedy this situation, we would need to hire additional staff or financial consultant support. We are assessing our capabilities to hire additional staff to facilitate greater segregation of duties.

Accordingly, as the result of identifying the above material weakness we have concluded that these control deficiencies resulted in a reasonable possibility that a material misstatement of the annual or interim financial statements may not be prevented or detected on a timely basis by the Company's internal controls.

Management believes that the material weaknesses set forth above were the result of the scale of our operations and are intrinsic to our small size. Management continues to take actions to remedy these weaknesses, including the review of current staff, reassignment of duties, and possible hiring of additional staff to create the necessary segregation of duties to improve controls over information processing.

Remediation Plan

We are starting the process of documenting, reviewing and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which requires annual management assessment of the effectiveness of our internal control over financial reporting. To comply with the requirements of being a public company, the Company has undertaken various actions, and will take additional actions, such as remediating the material weaknesses described above, implementing additional internal controls and procedures and hiring internal audit staff or financial consultants. While we believe that these remediation actions will improve the effectiveness of our internal control over financial reporting, the material weakness identified will not be considered remediated until the controls operate for a sufficient period of time, and we cannot assure you that the measures we have taken to date, or any measures we may take in the future will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses.

Changes in Internal Control over Financial Reporting

Other than the remediation efforts described above, there were no changes in our internal controls over financial reporting during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1: LEGAL PROCEEDINGS

From time to time in the normal course of our business operations, we may become subject to litigation that may result in liability material to our financial condition as a whole or may negatively affect our operating results if changes to our business operations are required. The cost to defend such litigation may be significant and may require a significant diversion of our resources, and there is no guarantee that we will be able to successfully defend against any such litigation regardless of particular merits. There also may be adverse publicity associated with litigation that could negatively affect customer perception of our business, regardless of whether the allegations are valid or whether we are ultimately found liable. Insurance may not be available on favorable terms, at all, or in sufficient amounts to cover any liabilities with respect to these or other matters. A judgment or other liability in excess of our insurance coverage for any claims could adversely affect our business, financial condition and the results of our operations.

Please reference the Litigation section of Note 11 to the unaudited financial statements for additional disclosure.

ITEM 1A: RISK FACTORS

Not applicable.

ITEM 2: UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Unregistered Sales of Equity Securities

On January 1, 2024, the Company issued 75,000 shares of common stock to Brian Hannash in exchange for consulting services related to the Company's transition to a public company.

On January 22, 2024, the Company received proceeds of \$26,180 from Exchange Listing, LLC upon the exercise of 11,000 common stock warrants at an exercise price of \$2.38.

On each of February 9, 2024, February 13, 2024, February 14, 2024, February 23, 2024, March 8, 2024, March 11, 2024, March 13, 2024 and March 14, 2024 the Company entered into securities purchase agreements (the "February and March 2024 SPAs") with a total of nine accredited investors for the issuance and purchase of convertible promissory notes (the "February and March 2024 Notes") for an aggregate purchase price of \$1,135,000. The February and March 2024 Notes bear an interest rate of 8.5% per annum, which shall be payable quarterly by the Company in cash or in shares of the Company's common stock at the conversion price as defined in the form of the Certificate of Designation of the Series B Convertible Preferred Stock (the "Series B Preferred Stock Certificate of Designation").

On February 12, 2024, in connection with the February and March 2024 SPAs and a securities purchase agreement (the "November SPA") with Flagstaff International, LLC ("Flagstaff International"), dated November 9, 2023, for the issuance and purchase of the Company's Series B Convertible Preferred Stock, par value \$0.001 per share (the "Series B Preferred Stock"), at a price per share of \$2.38, for an aggregate purchase price is \$3,000,000, the Company and Flagstaff International entered into a First Amendment to the November SPA (the "First Amendment"). The First Amendment provides for the issuance and purchase of a convertible promissory note with substantially the same terms as the February and March 2024 Notes. The Company agreed to obtain stockholders approval of an amendment to the Company's Certificate of Incorporation to authorize the creation of the Series B Preferred Stock (the "Stockholder Approval") and file the Series B Preferred Stock Certificate of Designation with the Secretary of State of the State of Delaware following the Stockholder Approval.

In February 2024, the Company and Flagstaff entered into a non-material second amendment to the SPA obligating the Company to file a resale registration statement for the Common Stock underlying the Series B Preferred Stock within fifteen (15) business days following the date of the Stockholder Approval.

On March 22, 2024, the Company and Flagstaff entered into the third amendment to the November SPA (the “Third Amendment”) to increase the investment amount from \$3,000,000 to \$5,000,000 and to modify the terms from the sale and issuance of the Series B Preferred Stock to the sale and issuance of a convertible promissory note. Pursuant to the Third Amendment, the November SPA was amended to provide that the Company shall sell to Flagstaff International a convertible promissory note (the “Flagstaff Note”) for an aggregate purchase price of \$5,000,000, to be paid to the Company in fifteen (15) monthly installments of differing amounts. Upon obtaining the Stockholder Approval and the filing of the Series B Preferred Stock Certificate of Designation with the Secretary of State of the State of Delaware, the Flagstaff Note will be convertible into a total of 2,100,841 shares of Series B Preferred Stock in lieu of Flagstaff International funding amounts under the Flagstaff Note to the Company for a purchase amount equal to each monthly purchase amount set forth in the Third Amendment.

On April 4, 2024, the Company issued 53,063 shares of common stock to Leonite Fund I, LP to settle a 2023 convertible note dispute.

Unless otherwise stated above, the issuances of these securities were made in reliance upon exemptions provided by Section 4(a)(2) of the Securities Act, Regulation D promulgated thereunder, or Securities Act Rule 701 for the offer and sale of securities not involving a public offering.

ITEM 3: DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5: OTHER INFORMATION.

During the quarter ended March 31, 2024, no director or officer of the Company adopted or terminated any “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

Exhibit Number	Exhibit Description
10.1	<u>Form of Securities Purchase Agreement (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on February 15, 2024)</u>
10.2	<u>Form of Convertible Promissory Note (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on February 15, 2024)</u>
10.3	<u>Form of Registration Rights Agreement (incorporated by reference to exhibit 10.3 to current report on Form 8-K, furnished to the SEC on February 15, 2024)</u>
10.4	<u>First Amendment to Securities Purchase Agreement (incorporated by reference to exhibit 10.4 to current report on Form 8-K, furnished to the SEC on February 15, 2024)</u>
10.5	<u>Third Amendment to Securities Purchase Agreement, dated March 22, 2024, between the Company and Flagstaff International, LLC (incorporated by reference to exhibit 10.1 to current report on Form 8-K, furnished to the SEC on March 28, 2024)</u>
10.6	<u>Form of Convertible Promissory Note issued to Flagstaff International, LLC (incorporated by reference to exhibit 10.2 to current report on Form 8-K, furnished to the SEC on March 28, 2024)</u>
31.1*	<u>Certification pursuant to 18 U.S.C. Section 1350 Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Executive Officer</u>
31.2*	<u>Certification pursuant to 18 U.S.C. Section 1350 Section 302 of the Sarbanes-Oxley Act of 2002 - Chief Financial Officer</u>
32.1**	<u>Certification pursuant to 18 U.S.C. Section 1350 Section 906 of the Sarbanes-Oxley Act of 2002 - Chief Executive Officer</u>
32.2**	<u>Certification pursuant to 18 U.S.C. Section 1350 Section 906 of the Sarbanes-Oxley Act of 2002 - Chief Financial Officer</u>
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** Furnished herewith

SIGNATURES

Pursuant to the requirements 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.

Date: May 20, 2024

NEURAXIS, INC.

By: /s/ Brian Carrico

Brian Carrico
Chief Executive Officer
(Principal Executive Officer)

Date: May 20, 2024

/s/ Timothy Henrichs

Timothy Henrichs
Chief Financial Officer
(Principal Financial and Principal Accounting Officer)

SECTION 302 CERTIFICATION

I, Brian Carrico, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended on March 31, 2024 of Neuraxis, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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.
5. The registrant's other certifying officer(s) and I have disclosed, based on Neuraxis, Inc.'s 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 (of 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 small business issuer's internal control over financial reporting.

Date: May 20, 2024

By: /s/ Brian Carrico
Brian Carrico
Chief Executive Officer

SECTION 302 CERTIFICATION

I, Timothy Henrichs, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended on March 31, 2024 of Neuraxis, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (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.
5. The registrant's other certifying officer(s) and I have disclosed, based on Neuraxis, Inc.'s 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 (of 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 small business issuer's internal control over financial reporting.

Date: May 20, 2024

By: /s/ Timothy Henrichs
Timothy Henrichs
Chief Financial Officer

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Neuraxis, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 (the "Report") I, Brian Carrico, Chief Executive Officer of the Company, certify, pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge and belief:

- (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.

Date: May 20, 2024

By: /s/ Brian Carrico

Brian Carrico
Chief Executive Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Neuraxis, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 (the "Report") I, Timothy Henrichs, Chief Financial Officer of the Company, certify, pursuant to 18 USC Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge and belief:

- (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.

Date: May 20, 2024

By: /s/ Timothy Henrichs

Timothy Henrichs
Chief Financial Officer

This certification accompanies the Report pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.
