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

FORM 10-Q

(Mark One)

X **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended September 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from ____ to ____

Commission file number: 001-38634

Reviva Pharmaceuticals Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**85-4306526**
(State or other jurisdiction of incorporation or organization**)**	**(I.R.S. Employer Identification No.)**
10080 N. Wolfe Road, Suite SW3-200 **Cupertino, CA** **(Address of principal executive offices)**	**95014** **(Zip Code)**

(408) 501-8881
(Registrant's telephone number, including area code)

Not applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	RVPH	The Nasdaq Capital Market
Warrants to purchase one share of Common Stock	RVPHW	The Nasdaq Capital Market

---

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 X No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes X 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 ☐	Accelerated filer ☐
Non-accelerated filer X	Smaller reporting company X Emerging growth company ☐

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

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

As of November 12, 2024 the number of outstanding shares of the registrant's common stock, par value $0.0001 per share, was 33,441,199.

REVIVA PHARMACEUTICALS HOLDINGS, INC.
FORM 10-Q TABLE OF CONTENTS

EXPLANATORY NOTE

As previously reported by Reviva Pharmaceuticals Holdings, Inc. (together with its consolidated subsidiary, the "Company", "we" or "us"), the audit committee (the "audit committee") of the board of directors of the Company, after meeting with management, concluded that the Company's previously issued financial statements for the fiscal year ended December 31, 2022 included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2022, the interim financial statements for the quarterly period ended September 30, 2022 included in its Quarterly Report on Form 10-Q, and each of the interim financial statements for the quarterly periods in fiscal 2023 included in its Quarterly Reports on Form 10-Q (cumulatively, the "Restatement Periods") should be restated to correct historical errors related principally to the timing of recognition of the Company's estimated accrual of certain research and development expenses. Such restatement was reflected and included within the Company's annual financial statements for the fiscal year ended December 31, 2023 included in its Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the Securities and Exchange Commission (the "SEC") on April 15, 2024.

Please refer to the Explanatory Note to the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on April 15, 2024, for more information regarding the restatement. For a more detailed discussion of the correction of historical errors in the Restatement Periods, including for the three and nine months ended September 30, 2023, refer to Notes 2 and 10 to the consolidated financial statements of the Company included in Part II, Item 8 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, which was filed with the SEC on April 15, 2024.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)
September 30, 2024 and December 31, 2023

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$ 5,558,817	$ 23,367,456
Prepaid clinical trial costs	925,526	78,295
Prepaid expenses and other current assets	325,808	254,637
Total current assets	6,810,151	23,700,388
Non-current prepaid clinical trial costs	819,721	—
Total Assets	$ 7,629,872	$ 23,700,388
Liabilities and Stockholders' Equity (Deficit)		
Liabilities		
Short-term debt	$ 83,000	$ —
Accounts payable	8,777,579	3,849,108
Accrued clinical expenses	7,362,666	11,966,812
Accrued compensation	881,830	958,607
Other accrued liabilities	428,801	400,490
Total current liabilities	17,533,876	17,175,017
Warrant liabilities	77,884	806,655
Total Liabilities	17,611,760	17,981,672
Commitments and contingencies (Note 6)		
Stockholders' Equity (Deficit)		
Common stock, par value of $0.0001; 115,000,000 shares authorized; 33,441,199 and 27,918,560 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	3,344	2,792
Preferred Stock, par value of $0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	148,028,341	140,070,172
Accumulated deficit	(158,013,573)	(134,354,248)
Total stockholders' equity (deficit)	(9,981,888)	5,718,716
Total Liabilities and Stockholders' Equity (Deficit)	$ 7,629,872	$ 23,700,388

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

For the Three and Nine Months Ended September 30, 2024 and 2023

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses		(as restated)		(as restated)
Research and development	$ 6,858,285	$ 9,572,180	$ 18,226,497	$ 23,312,661
General and administrative	1,604,249	1,991,774	6,287,786	6,571,629
Total operating expenses	8,462,534	11,563,954	24,514,283	29,884,290
Loss from operations	(8,462,534)	(11,563,954)	(24,514,283)	(29,884,290)
Other income (expense)				
Gain (loss) on remeasurement of warrant liabilities	72,321	139,079	728,771	(305,972)
Interest expense	(5,146)	(5,901)	(13,786)	(20,414)
Interest income	53,248	91,763	313,956	341,854
Other income (expense), net	(23,687)	5,194	(159,202)	(15,220)
Total other income, net	96,736	230,135	869,739	248
Loss before provision for income taxes	(8,365,798)	(11,333,819)	(23,644,544)	(29,884,042)
Provision for income taxes	—	12,117	14,781	21,531
Net loss	$ (8,365,798)	$ (11,345,936)	$ (23,659,325)	$ (29,905,573)
Net loss per share:				
Basic and diluted	$ (0.25)	$ (0.48)	$ (0.75)	$ (1.32)
Weighted average shares outstanding				
Basic and diluted	33,804,693	23,637,367	31,424,395	22,655,737

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)

For the Three and Nine Months Ended September 30, 2024

Three Months Ended September 30, 2024	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
Balance at June 30, 2024	29,817,294	$ 2,982	$ 143,603,271	$ (149,647,775)	$ (6,041,522)
Common stock issued in connection with prefunded warrant exercises	347,643	35	—	—	35
Issuance of common stock in offering, net of transaction costs	3,276,262	327	1,036,813	—	1,037,140
Issuance of common stock warrants in offering, net of transaction costs	—	—	1,229,010	—	1,229,010
Issuance of prefunded stock warrants in offering, net of transaction costs	—	—	470,057	—	470,057
Issuance of underwriter warrants in offering	—	—	165,952	—	165,952
Modification of existing warrants, net of transaction costs	—	—	844,366	—	844,366
Stock-based compensation expense	—	—	348,056	—	348,056
Settlement of bonuses in form of stock options	—	—	330,816	—	330,816
Net loss	—	—	—	(8,365,798)	(8,365,798)
Balance at September 30, 2024	33,441,199	$ 3,344	$ 148,028,341	$ (158,013,573)	$ (9,981,888)

Nine Months Ended September 30, 2024	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2023	27,918,560	$ 2,792	$ 140,070,172	$ (134,354,248)	$ 5,718,716
Common stock issued in connection with prefunded warrant exercises	347,643	35	—	—	35
Issuance of common stock in offering, net of transaction costs	5,174,996	517	2,531,104	—	2,531,621
Issuance of common stock warrants in offering, net of transaction costs	—	—	2,310,699	—	2,310,699
Issuance of prefunded warrants in offering, net of transaction costs	—	—	470,057	—	470,057
Issuance of underwriter warrants in offering	—	—	165,952	—	165,952
Modification of existing warrants, net of transaction costs	—	—	1,073,416	—	1,073,416
Stock-based compensation expense	—	—	1,076,125	—	1,076,125
Settlement of bonuses in form of stock options	—	—	330,816	—	330,816
Net loss	—	—	—	(23,659,325)	(23,659,325)
Balance at September 30, 2024	33,441,199	$ 3,344	$ 148,028,341	$ (158,013,573)	$ (9,981,888)

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT) (UNAUDITED)

For the Three and Nine Months Ended September 30, 2023

Three Months Ended September 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit (as restated)	Total Stockholders' Deficit (as restated)
Balance at June 30, 2023 (as restated)	22,650,266	$ 2,265	$ 111,835,588	$ (113,653,048)	$ (1,815,195)
Stock-based compensation expense	—	—	350,410	—	350,410
Net loss (as restated)	—	—	—	(11,345,936)	(11,345,936)
Balance at September 30, 2023 (as restated)	$ 22,650,266	$ 2,265	$ 112,185,998	$ (124,998,984)	$ (12,810,721)

Nine Months Ended September 30, 2023	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Deficit (as restated)	Total Stockholders' Equity (Deficit) (as restated)
Balance at December 31, 2022 (as restated)	20,447,371	$ 2,045	$ 103,485,612	$ (95,093,411)	$ 8,394,246
Common stock issued in connection with warrant exercises	2,202,895	220	5,677,630	—	5,677,850
Stock-based compensation expense	—	—	3,022,756	—	3,022,756
Net loss (as restated)	—	—	—	(29,905,573)	(29,905,573)
Balance at September 30, 2023 (as restated)	$ 22,650,266	$ 2,265	$ 112,185,998	$ (124,998,984)	$ (12,810,721)

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

For the Nine Months Ended September 30, 2024 and 2023

	Nine Months Ended September 30,	
	2024	**2023**
		(as restated)
Cash flows from operating activities		
Net loss	$ (23,659,325)	$ (29,905,573)
Adjustments to reconcile net loss to net cash used in operating activities		
Change in fair value of warrant liabilities	(728,771)	305,972
Stock-based compensation expense	1,076,125	3,022,756
Changes in operating assets and liabilities:		
Prepaid clinical trial costs (current and non-current)	(1,666,952)	—
Prepaid expenses and other current assets	(71,171)	(10,924)
Accounts payable	4,928,471	1,758,104
Accrued expenses and other current liabilities	(4,321,796)	5,381,757
Net cash used in operating activities	(24,443,419)	(19,447,908)
Cash flows from financing activities		
Proceeds from issuance of short-term debt	415,000	667,500
Repayment of short-term debt	(332,000)	(445,000)
Proceeds from issuance of common stock, common stock warrants, prefunded warrants and from modification of existing warrants, in offering, net of issuance costs	6,551,745	—
Proceeds from exercise of warrants	35	5,677,850
Net cash provided by financing activities	6,634,780	5,900,350
Net decrease in cash and cash equivalents	(17,808,639)	(13,547,558)
Cash and cash equivalents, beginning of period	23,367,456	18,519,856
Cash and cash equivalents, end of period	$ 5,558,817	$ 4,972,298
Supplemental disclosures of cash flow information:		
Cash paid for taxes	$ 3,417	$ 18,674
Cash paid for interest	$ 13,786	$ 20,414
Noncash Investing and Financing Activities:		
Settlement of bonuses in form of stock options	$ 330,816	$ —
Warrant modification recorded in stockholders' deficit	$ 1,073,416	$ —
Issuance of common stock warrants	$ 2,310,699	
Issuance of underwriter warrants	$ 165,952	$ —

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

1. ORGANIZATION AND NATURE OF OPERATIONS

On December 14, 2020, Reviva Pharmaceuticals Holdings, Inc. (the "Company"), a Delaware corporation and the successor by re-domiciliation to Tenzing Acquisition Corp. ("Tenzing"), a British Virgin Islands exempted company, Tenzing Merger Subsidiary Inc., a Delaware corporation and wholly-owned subsidiary of Tenzing ("Merger Sub"), and Reviva Pharmaceuticals, Inc., a Delaware corporation (together with its consolidated subsidiary), consummated a business combination (the "Business Combination") through the merger of Merger Sub with and into Reviva Pharmaceuticals, Inc. (the "Merger"), in accordance with the Agreement and Plan of Merger, dated as of July 20, 2020 (the "Merger Agreement"), by and among Tenzing, Merger Sub, Reviva Pharmaceuticals, Inc., and the other parties thereto. Pursuant to the Merger Agreement, at the effective time of the Merger, Merger Sub merged with and into Reviva Pharmaceuticals, Inc., with Reviva Pharmaceuticals, Inc. as the surviving company in the Merger and, after giving effect to such Merger, Reviva Pharmaceuticals, Inc. becoming a wholly-owned subsidiary of Reviva Pharmaceuticals Holdings, Inc. In these notes to the unaudited condensed consolidated financial statements, unless otherwise specified or the context indicates otherwise, references to the "Company," "Reviva," "we," "us" and "our" refer to Reviva Pharmaceuticals Holdings, Inc. and its consolidated subsidiary.

Reviva Pharmaceuticals, Inc. was originally incorporated in the state of Delaware and commenced operations on May 1, 2006 and its Indian subsidiary, Reviva Pharmaceuticals India Pvt. Ltd. was incorporated in 2014. The Company is a late-stage pharmaceutical company developing new therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), inflammatory and cardiometabolic diseases.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND BASIS OF PRESENTATION

Basis of presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X. Certain footnotes and other financial information normally required by accounting principles generally accepted in the United States of America, or U.S. GAAP, have been condensed or omitted in accordance with such rules and regulations. In management's opinion, these unaudited condensed consolidated financial statements have been prepared on the same basis as our annual consolidated financial statements and notes thereto and include all adjustments, consisting of normal recurring items, considered necessary for the fair presentation. The operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2024.

The unaudited condensed consolidated balance sheet as of December 31, 2023, has been derived from our audited financial statements at that date but does not include all disclosures and financial information required by U.S. GAAP for complete financial statements. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated financial statements and notes thereto for the year ended December 31, 2023, which were included in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission ("SEC") on April 15, 2024.

Reclassifications

Certain amounts in the prior year's consolidated financial statements, as of December 31, 2023 have been reclassified to conform to the current period's presentation. This involved disclosing separately, prepaid clinical trial costs from the prepaid expenses and other current assets balance, which were previously disclosed in the aggregate. This reclassification had no effect on the Company's loss from operations, net loss, or net loss per share.

Principles of consolidation

The accompanying condensed consolidated financial statements include the accounts of Reviva Pharmaceuticals Holdings, Inc. and its wholly owned subsidiary Reviva Pharmaceuticals, India Pvt Ltd. The Company's subsidiary's functional currency is the U.S. dollar. The Company recognizes a foreign currency gain or loss each reporting period, on translation of its foreign subsidiary's financial information on consolidation. Any such foreign currency gain or loss is recognized as part of other expense, net, on the condensed consolidated statement of operations. The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. All transactions and balances between the parent and its subsidiary have been eliminated in consolidation.

Previously-disclosed restatement of previously reported interim condensed consolidated quarterly financial statements

The interim consolidated financial statements include corrections to the three and nine months ended September 30, 2023, which corrections were previously presented in the audited consolidated financial statements and notes thereto, including specifically Note 10, "*Quarterly Financial Data (Unaudited and Restated)*", for the fiscal year ended December 31, 2023, included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC on April 15, 2024 (sometimes hereinafter referred to as the "2023 Form 10-K").

As previously reported in Item 4.02(a) of the Company's Current Report on Form 8-K as filed with the SEC on April 15, 2024, and in the Company's 2023 Form 10-K, on April 12, 2024, the audit committee (the "audit committee") of the board of directors of the Company, after meeting with management, concluded that the Company's previously issued financial statements for the fiscal year ended December 31, 2022 included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, the interim financial statements for the quarterly period ended September 30, 2022 included in its Quarterly Report on Form 10-Q, and each of the interim financial statements for the quarterly periods in fiscal 2023 included in its Quarterly Reports on Form 10-Q (cumulatively, the "Restatement Periods") should be restated to correct historical errors related principally to the timing of recognition of the Company's estimated accrual of certain research and development expenses.

The need for the restatement arose out of the results of certain financial analysis the Company performed in the course of preparing its fiscal year-end 2023 consolidated financial statements. Principally, the Company completed a detailed lookback analysis to compare certain estimated accrued clinical trial expenses, specifically investigator fees, from one contract research organization to its actual clinical trial expenses that were incurred for the respective periods for that contract research organization during the Restatement Periods based on review of historical invoices. In the course of its analysis of the actual information gathered through the lookback process, the Company detected differences between the estimated accrued amounts of those clinical trial expenses and the actual expenses recorded due primarily to the Company's failure to properly review and evaluate expenses incurred in those clinical trial contracts resulting in the Company not properly accruing for clinical trial expenses that were incurred but for which invoices were not yet received. In addition, the Company determined that an effective process for evaluating the completeness of the research and development expense accrual for investigator fees and related costs, for that contract research organization, was necessary. This included estimated patient site visits not yet reported, average site visit costs and average delay in site invoicing. This provides the Company with an effective estimate of the costs incurred as there can be a lag between receiving an invoice for the services provided from that contract research organization. Management and the audit committee of the Company's board of directors concluded that, in the ordinary course of closing its financial books and records, the Company previously excluded certain clinical trial expenses and associated accruals from the appropriate periods as required under applicable accounting guidelines. Therefore, the Company misstated research and development expenses, and accrued clinical expenses for the three and nine months ended September 30, 2023.

As previously disclosed, the Company misstated research and development expenses and associated accrued liabilities during the Restatement Periods. Also as previously disclosed, the Company principally attributes the errors to a material weakness in its internal control activities due to a failure in the design and implementation of its controls to review clinical trial expenses, including the evaluation of the terms of clinical trial contracts. Specifically, the Company failed to properly review and evaluate progress of expenses incurred in clinical trial contracts resulting in the Company not properly accruing for clinical trial expenses that were incurred but for which invoices were not yet received. These material weaknesses were previously disclosed in Item II, Part 9A of the Company's 2023 Form 10-K, and are disclosed in Part I, Item 4 of this Quarterly Report on Form 10-Q. The Company has commenced procedures to remediate the material weaknesses. However, these material weaknesses will not be considered remediated until the applicable remedial actions have been fully implemented and the Company has concluded that these controls are operating effectively for a sufficient period of time.

These condensed consolidated financial statements and the corresponding discussion included in Part I, Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, are reflective of the restatement adjustments for the three and nine months ended September 30, 2023, as previously presented in Note 10 to the Company's consolidated financial statements included in the 2023 Form 10-K.

As previously disclosed in Note 10, "*Quarterly Financial Data (Unaudited and Restated)*", to the Consolidated Financial Statements included in the Company's 2023 Form 10-K, the restated line items of the consolidated statement operations for three and nine months ended September 30, 2023 are as follows:

	Originally Reported	Adjustment	Restated
	Three Months Ended September 30, 2023	Three Months Ended September 30, 2023	Three Months Ended September 30, 2023
Research and development	$ 8,717,273	$ 854,907	$ 9,572,180
Total operating expenses	10,709,047	854,907	11,563,954
Loss from operations	(10,709,047)	(854,907)	(11,563,954)
Net loss	(10,491,029)	(854,907)	(11,345,936)
Basic and diluted	$ (0.44)	$ (0.04)	$ (0.48)

	Originally Reported	Adjustment	Restated
	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Research and development	$ 22,943,522	$ 369,139	$ 23,312,661
Total operating expenses	29,515,151	369,139	29,884,290
Loss from operations	(29,515,151)	(369,139)	(29,884,290)
Net loss	(29,536,434)	(369,139)	(29,905,573)
Basic and diluted	$ (1.30)	$ (0.02)	$ (1.32)

While the adjustments changed net loss, and accrued expenses and other current liabilities line items in the condensed consolidated cash flow statement, they did not have an impact on total net cash used in operating activities. Further, there was no impact on cash flows from investing or cash flows from financing activities.

As previously disclosed in Note 10, "*Quarterly Financial Data (Unaudited and Restated)*", to the Consolidated Financial Statements included in the Company's 2023 Form 10-K, the restated line items of the consolidated cash flow statement for the nine months ended September 30, 2023 are as follows:

	Originally Reported	Adjustment	Restated
	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Cash flows from operating activities			
Net loss	$ (29,536,434)	$ (369,139)	$ (29,905,573)
Adjustments to reconcile net loss to net cash used in operating activities			
Changes in operating assets and liabilities			
Accrued expenses and other current liabilities	5,012,618	369,139	5,381,757
Net cash used in operating activities	$ (19,447,908)	$ —	$ (19,447,908)

Liquidity and going concern

The Company has incurred losses since inception and as of September 30, 2024 the Company had a working capital deficit of approximately $10.7 million, an accumulated deficit of $158.0 million and cash and cash equivalents on hand of approximately $5.6 million. The Company's net loss for the three months ended September 30, 2024 and 2023, was approximately $8.4 million and $11.3 million, respectively. The Company's net loss for the for the nine months ended September 30, 2024 and 2023, was approximately $23.7 million and $29.9 million, respectively. The Company expects to incur significant expenses and increased operating losses for the next several years. The Company expects its expenses to increase in connection with its ongoing activities to research, develop and commercialize its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

The Company's current cash on hand is not sufficient to satisfy its operating cash needs for the 12 months from the filing of this Quarterly Report on Form 10-Q. The Company believes that it has adequate cash on hand to cover anticipated outlays into the end of the fourth quarter of 2024. The Company has based this estimate, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than it currently expects. The Company will need to raise additional funds to continue funding its development efforts and operations. The Company intends to secure such additional funding, although there are no guarantees or commitments for additional funding. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. The Company will seek to fund its operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. In May 2024 and August 2024, the Company raised capital through registered financial offerings (Note 4). Adequate additional financing may not be available to the Company on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain clinical activities. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued.

Use of estimates

The preparation of condensed consolidated financial statements in conformity with 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 as of the date of the financial statements and the reported amounts of expenses during the reporting periods covered by the financial statements and accompanying notes. Significant areas requiring the use of management estimates include, but are not limited to, accounting for clinical trial costs, assumptions used to calculate the fair value of stock-based compensation, assumptions used to calculate the fair value of warrants, deferred taxes, and related valuation allowances. Actual results could differ materially from such estimates under different assumptions or circumstances.

Concentration of credit risk and other risks and uncertainties

Financial instruments that potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents. Substantially, all the Company's cash and cash equivalents are held in demand deposit and money market funds at three financial institutions. Deposits in financial institutions may, from time to time, exceed federally insured limits. Amounts held in demand deposit in excess of federally insured limits, totaled $1,027,696 and $786,971 as of September 30, 2024 and December 31, 2023, respectively. The Company has not experienced any losses on its deposits of cash.

The Company is subject to all of the risks inherent in a clinical-stage company developing new pharmaceutical products. These risks include, but are not limited to, limited management resources, dependence upon medical acceptance of the product in development, regulatory approvals, successful clinical trials, availability and willingness of patients to participate in human trials, and competition in the pharmaceutical industry. The Company's operating results may be materially affected by the foregoing factors.

Cash and cash equivalents

As of September 30, 2024, and December 31, 2023, the Company's cash was maintained in demand deposit forms at three financial institutions. The Company considers any highly liquid investments, such as money market funds, with an original maturity of three months or less to be cash and cash equivalents.

The components of cash and cash equivalents were as follows:

	As of September 30, 2024	As of December 31, 2023
Cash on deposit	$ 1,363,860	$ 1,155,636
Money market funds (cash equivalents)	4,194,957	22,211,820
Cash and cash equivalents	$ 5,558,817	$ 23,367,456

Fair Value Measurements

Accounting Standards Codification ("ASC") 820, *Fair Value Measurements* ("ASC 820"), defines fair value, establishes a framework for measuring fair value in U.S. GAAP and expands disclosures about fair value measurements. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three broad levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels of the fair value hierarchy under ASC 820 are described below:

- Level 1 - Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

- Level 2 - Directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

- Level 3 - Unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining the fair value of all warrants, excluding the private-placement warrants (see Note 4), the Company utilizes the Black-Scholes model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected divided rate, and risk-free interest rates. In determining the fair value of the private placement warrants, the Company utilizes a Lattice model using assumptions regarding volatility implied by public warrant market price, expected term of the warrants, expected dividend rate, and risk-free interest rates. Due to their short maturities, the carrying amounts for cash and cash equivalents, prepaid clinical trial costs, prepaid expenses and other current assets, accounts payable, accrued clinical expenses, accrued compensation, short-term debt, and other accrued liabilities approximate their fair value.

Short-term debt

In January 2024, the Company obtained financing for certain Director and Officer liability insurance policy premiums. The governing agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies.

The total premiums, taxes, and fees financed was $518,750, of which of which a principal balance of $415,000 was financed after accounting for the up-front payment made. The financing arrangement has an annual percentage interest rate of 7.99% and a term of 12 months, with payments, inclusive of interest, payable on a monthly basis.

New accounting pronouncements not yet adopted

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures*. This Update improves reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses. The amendments in this Update are effective for fiscal years beginning after December 15, 2023 and interim periods within fiscal years beginning after December 15, 2024. Early adoption of the amendments is permitted. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes* (Topic 740), *Improvements to Income Tax Disclosures*. This Update enhances the transparency and usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The guidance also eliminates certain existing requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The amendments in this Update are effective for annual periods beginning after December 15, 2024. Early adoption of the amendments is permitted for annual financial statements that have not yet been issued. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, to require disclosure, in the notes to financial statements, of specified information about certain costs and expenses. The effective date for the standard is for fiscal years beginning after December 15, 2026 and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is in the process of evaluating the impact of this new guidance on its consolidated financial statements.

3. LOSS PER SHARE

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net loss per share includes potentially dilutive securities such as stock options, warrants to purchase common stock (excluding warrants that are exercisable for $0.0001 per warrant), and shares contingently issuable for earnout unless the result of inclusion would be anti-dilutive. These securities have been excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2024 and 2023, because all such securities are anti-dilutive for all periods presented.

The components of basic and diluted net loss per share were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023 (as restated)	2024	2023 (as restated)
Numerator:				
Net loss	$ (8,365,798)	$ (11,345,936)	$ (23,659,325)	$ (29,905,573)
Denominator:				
Weighted-average common shares outstanding – basic and diluted	33,804,693	23,637,367	31,424,395	22,655,737
Net loss per share – basic and diluted	$ (0.25)	$ (0.48)	$ (0.75)	$ (1.32)

The following table summarizes the Company's potentially dilutive securities, in common share equivalents, which have been excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Shares issuable upon exercise of stock options	1,813,387	1,687,774	1,813,387	1,687,774
Shares issuable upon exercise of warrants to purchase common stock (excluding warrants that are exercisable for $0.0001 per warrant)	27,782,603	15,030,209	27,782,603	15,030,209
Shares contingently issuable for earnout	—	1,000,000	—	1,000,000
	29,595,990	17,717,983	29,595,990	17,717,983

The diluted net loss per share computation equals basic net loss per share for the three and nine months ended September 30, 2024 and 2023 because the Company had a net loss and the impact of the assumed exercise of stock options, certain warrants, and shares contingently issuable for earnout would have been anti-dilutive.

4. WARRANTS

Warrant activity during nine months ended September 30, 2024, was as follows:

	Number of Warrants	Number of Shares Underlying Warrants	Weighted Average Exercise Price	Total Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
Outstanding as of December 31, 2023	25,067,643	22,852,634	$ 6.03	$ 29,686,123	3.1
Issued	8,384,377	8,384,377	0.82	—	4.8
Exercised	(347,643)	(347,643)	0.0001	—	4.9
Outstanding as of September 30, 2024	33,104,377	30,889,368	$ 4.01	$ 7,568,550	3.4

The difference reflected between the number of warrants and the number of shares underlying the warrants, is the result of an aggregate of 8,860,040 outstanding warrants, issued in 2021, for which each warrant is exercisable into 0.75 shares of common stock.

May 2024 Registered Direct Offering

On May 28, 2024, the Company entered into a securities purchase agreement (the "Purchase Agreement") pursuant to which the Company sold, in a registered direct offering (the "May 2024 Offering") priced at the market under Nasdaq rules which closed on May 29, 2024, an aggregate of (i) 1,898,734 shares of its common stock, and (ii) warrants (the "May 2024 Warrants") exercisable for an aggregate of up to 1,898,734 shares of its common stock. The public offering price for each share of common stock and accompanying May 2024 Warrant to purchase one share of common stock was $1.58. The May 2024 Warrants have a term of 5 years and expire on May 29, 2029. The net proceeds to the Company from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company, of $0.4 million.

The Company evaluated the May 2024 Warrants in accordance with the guidance at ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The May 2024 Warrants are indexed to the Company's common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the May 2024 Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The fair value of the May 2024 Warrants was determined utilizing a Black-Scholes model, considering all relevant assumptions current at the date of issuance (i.e., Company stock price of $1.34, exercise price of $1.46, expected term of 5 years, volatility of 93%, risk-free interest rate of 4.6%, and expected dividend rate of 0%). Refer to Note 2 for further detail regarding how assumptions were determined. The grant date relative fair value of the May 2024 Warrants was estimated to be approximately $1.1 million recognized to additional paid-in capital in the condensed consolidated balance sheet as the May 2024 Warrants were determined to be equity classified, with the corresponding debit as an issuance cost of the related equity offering.

Accounting for Warrant Modification

In connection with the May 2024 Offering, on May 28, 2024, the Company entered into a warrant amendment agreement with the purchaser party to the Purchase Agreement, pursuant to which the Company agreed to amend the purchaser's existing warrants to purchase 1,365,854 shares of common stock at an exercise price of $5.00 per share issued in November 2023 (the "May 2024 Existing Warrants") in consideration for such purchaser party's participation and purchase of approximately $3.0 million of securities in the May 2024 Offering and the payment of $0.2 million to (i) lower the exercise price of the May 2024 Existing Warrants to $1.455 per share and (ii) amend the expiration date of the May 2024 Existing Warrants to five years following the closing of the May 2024 Offering, effective upon the closing of the May 2024 Offering on May 29, 2024.

ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815") require issuers to account for modifications or exchanges of freestanding equity-classified written call options (e.g., warrants) that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Pursuant to ASC 480 and ASC 815, the Company accounts for modifications of equity-classified warrant agreements by recording any increase in fair value of the modified equity-classified warrant as an equity issuance cost that reduces additional paid-in capital. The increase in the fair value of the modified May 2024 Existing Warrants was determined to be $0.2 million.

The following assumptions were used to value the modification of the May 2024 Existing Warrants immediately before the modification and immediately after the modification:

	Immediately before the modification	Immediately after the modification
Risk-free interest rate	4.70%	4.60%
Remaining expected term	4.5	5.0
Expected volatility	97.00%	93.00%
Stock price on valuation date	$ 1.34	$ 1.34
Exercise price	$ 5.00	$ 1.46
Expected dividend rate	—%	—%

August 2024 Underwritten Offering

On August 20, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Titan Partners Group LLC, a division of American Capital Partners, LLC, as the underwriter (the "Underwriter"), relating to the offering, issuance and sale of (i) 3,276,262 shares of common stock, (ii) pre-funded warrants (the "August 2024 Pre-Funded Warrants") exercisable for an aggregate of up to 1,485,643 shares of common stock, and (iii) warrants (the "August 2024 Warrants") exercisable for an aggregate of 4,761,905 shares of common stock (the "August 2024 Offering"). The public offering price for each share of common stock and accompanying August 2024 Warrant to purchase one share of common stock (including the pricing for the warrant repricing described below) was $1.05, and the public offering price for each August 2024 Pre-Funded Warrant and accompanying August 2024 Warrant to purchase one share of common stock was $1.0499. The net proceeds to the Company from the August 2024 Offering were approximately $3.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company of approximately $1.3 million. The August 2024 Offering closed on August 22, 2024.

The August 2024 Warrants are each exercisable for one share of common stock at an exercise price of $0.7964 per share and will expire five years from the issuance date. The August 2024 Pre-Funded Warrants are each exercisable for one share of common stock at an exercise price of $0.0001 per share and do not expire.

Upon the closing of the August 2024 Offering, the Company issued to the Underwriter warrants to purchase up to 238,095 shares of common stock (the "August 2024 Underwriter Warrants"). The August 2024 Underwriter Warrants will be exercisable at an exercise price of $ 1.3125 per share and are exercisable during the five-year period commencing six months after the closing date of the August 2024 Offering.

The Company evaluated the August 2024 Warrants and August 2024 Pre-funded Warrants in accordance with the guidance at ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The August 2024 Warrants are indexed to the common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the August 2024 Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The Company evaluated the August 2024 Underwriter Warrants in accordance with the guidance at ASC 718, *Compensation-Stock Compensation*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The August 2024 Underwriter Warrants are indexed to the common stock and are required to be settled through physical settlement, subject to certain conditions, or net share settlement, if exercised. Accordingly, the August 2024 Underwriter Warrants were recorded at their grant date fair value with no subsequent remeasurement. Further, the Company recognized the August 2024 Underwriter Warrants as a stock issuance costs as they are issued for services in connection with an offering, and therefore will account for these as a reduction of the proceeds in the August 2024 Offering.

The fair value of the August 2024 Warrants, August 2024 Pre-funded Warrants, and August 2024 Underwriter Warrants were determined utilizing a Black-Scholes model, considering all relevant assumptions current at the date of issuance (i.e., Company stock price of $0.90, exercise price of $0.7964 for the August 2024 Warrants, $ 0.0001 for the August 2024 Pre-funded Warrants, and $1.3125 for the August 2024 Underwriter Warrants, expected term of 5 years, applicable to all the warrants, volatility of 111%, applicable to all the warrants, risk-free interest rate of 3.7%, applicable to all of the warrants, and expected dividend rate of 0%, applicable to all the warrants). Refer to Note 2 for further detail regarding how assumptions were determined. The grant date relative fair value of the August 2024 Warrants, August 2024 Pre-funded Warrants and August 2024 Underwriter Warrants was estimated to be approximately $3.5 million, $1.3 million, and $0.2 million, respectively, and were recognized as additional paid-in capital in the condensed consolidated balance sheet as the August 2024 Warrants, August 2024 Pre-funded Warrants, and August 2024 Underwriter Warrants were determined to be equity classified, with the corresponding debit as an issuance cost of the related equity offering.

Accounting for Warrant Modification

In connection with the August 2024 Offering, on August 20, 2024, the Company entered into a warrant amendment agreement (the "August 2024 Warrant Amendment Agreement") with the purchaser of the August 2024 Pre-Funded Warrants, pursuant to which the Company agreed to amend the purchaser's (i) warrants to purchase up to 2,536,586 shares of common stock at an exercise price of $5.00 per share issued in November 2023 and (ii) warrants to purchase up to 2,199,975 shares of common stock at an exercise price of $4.125 per share issued in June 2021 (together, the "August 2024 Existing Warrants"), in consideration for such investor's participation in the August 2024 Underwritten Offering and the payment of $0.125 per August 2024 Existing Warrant (which amount is included in the $ 1.05 offering price above) to (i) lower the exercise price of the August 2024 Existing Warrants to $0.7964 per share and (ii) amend the expiration date of the August 2024 Existing Warrants to five years following the closing of the August 2024 Offering, effective upon the closing of the August 2024 Offering on August 22, 2024.

ASC Topic 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC Topic 815, *Derivatives and Hedging* ("ASC 815") require issuers to account for modifications or exchanges of freestanding equity-classified written call options (e.g., warrants) that remain equity classified after the modification or exchange based on the economic substance of the modification or exchange. Pursuant to ASC 480 and ASC 815, the Company accounts for modifications of equity-classified warrant agreements by recording any increase in fair value of the modified equity-classified warrant as an equity issuance cost that reduces additional paid-in capital. The increase in the fair value of the modified August 2024 Existing Warrants was determined to be $0.8 million.

The following assumptions were used to value the modification of the warrants immediately before and immediately after the modification:

	Immediately before the modification		Immediately after the modification	
	June 2021 Warrants	November 2023 Warrants	June 2021 Warrants	November 2023 Warrants
Risk-free interest rate	4.10%	3.70%	3.70%	3.70%
Remaining expected term	1.76	4.25	5.00	5.00
Expected volatility	100.00%	111.00%	111.00%	111.00%
Stock price on valuation date	$ 1.14	$ 1.14	$ 1.14	$ 1.14
Exercise price	$ 4.1250	$ 5.0000	$ 0.7964	$ 0.7964
Expected dividend rate	—%	—%	—%	—%

5. STOCKHOLDERS' EQUITY (DEFICIT), STOCK OPTION PLANS, AND STOCK-BASED COMPENSATION

Our authorized capital stock consists of:

- 115,000,000 shares of common stock, par value $0.0001 per share; and
- 10,000,000 shares of preferred stock, par value $0.0001 per share.

As of September 30, 2024 there were 33,441,199 shares of our common stock outstanding, and no shares of preferred stock outstanding.

On May 28, 2024, the Company entered into the Purchase Agreement for the sale of shares of common stock and the May 2024 Warrants. Refer to Note 4, Warrants, for additional details.

On August 20, 2024, the Company entered into the Underwriting Agreement for the offering, issuance, and sale of Common stock, the August 2024 Warrants and the August 2024 Pre-funded Warrants. Refer to Note 4, Warrants, for additional details.

As of September 30, 2024, the Company has shares of common stock reserved for future issuance as follows:

Shares underlying outstanding warrants	30,889,368
Shares reserved for future issuance under the 2020 Equity Incentive Plan	3,563,306
Stock options outstanding	1,813,387
Total common stock reserved for future issuance	36,266,061

2006 and 2020 Equity Incentive Plans

As of December 31, 2023, there were an aggregate of 1,004,263 shares of common stock available for issuance under the 2020 Equity Incentive Plan, subject to equitable adjustment in the event of stock splits and other capital changes (the "Share Reserve"). Following the December 31, 2023 balance sheet date, in accordance with the "evergreen" provision in our 2020 Equity Incentive Plan (the "Evergreen Provision"), an additional 2,791,856 shares were automatically made available for issuance on the first day of 2024, which represents 10% of the number of shares of common stock outstanding on December 31, 2023. As a result, as of September 30, 2024, the Share Reserve available for future awards under the 2020 Equity Incentive Plan stood at 3,563,306 shares, after accounting for the above described 2024 Evergreen Increase, options forfeited in the first, second and third quarters of 2024, and options granted in the third quarter of 2024.

As of September 30, 2024, the Share Reserve related to previously issued and outstanding awards under the 2006 Equity Incentive Plan stood at 16,747. No new grants of awards are permitted under the 2006 Equity Incentive Plan.

Stock-Based Compensation Expense

The Company records stock-based compensation expense based on the fair value of stock options granted to employees, non-employee consultants and non-employee directors. During the three months ended September 30, 2024 and 2023, the Company recorded stock-based compensation expense of approximately $0.3 million and $0.4 million, respectively. During the nine months ended September 30, 2024 and 2023, the Company recorded stock-based compensation expense of approximately $1.1 million and $3.0 million, respectively. As of September 30, 2024 the Company had unrecognized stock-based compensation expense of $2.1 million, which is expected to be recognized over a weighted-average period of 1.8 years.

Determining Fair Value

Valuation and Recognition – The fair value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes pricing model utilizes the following assumptions:

- Expected Term – Expected life of an option award is the average length of time over which the Company expects employees will exercise their options, which is based on historical experience with similar grants.
- Expected Volatility - Expected volatility is based on historical stock volatility data, for a peer set of similar public Company's with sufficient trading history, over the expected term of the awards.
- Risk-Free Interest Rate - The Company bases the risk-free interest rate on the implied yield currently available on U.S. Treasury zero-coupon issues with an equivalent expected term.
- Dividend Yield – The Company has not paid a dividend and does not anticipate paying a dividend in the foreseeable future.

The fair value of options granted during the three and nine months ended September 30, 2024 used the following assumptions:

Black-Scholes Inputs

	September 30, 2024
Risk-free interest rate	3.37%
Expected term (in years)	5.00
Expected volatility	118.00%
Expected dividend yield	—%

The weighted average fair value of stock options granted during the three and nine months ended September 30, 2024, was $0.3 million, respectively.

Activity under the stock plans for the nine months ended September 30, 2024 is as follows:

	Shares Available for Grant	Number of Options Outstanding	Weighted Average Exercise price per share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance, December 31, 2023	1,004,263	1,580,574	$ 6.51	9.11	$ 300,969
Granted*	(332,813)	332,813	$ 1.20		
Expired	100,000	(100,000)	$ 6.74		
Evergreen plan increase	2,791,856				
Balance, September 30, 2024	3,563,306	1,813,387	$ 5.52	8.65	$ 83,525
Options exercisable at September 30, 2024		1,322,945	$ 5.29	8.65	$ 83,295

* During the nine months ended September 30, 2024, the Company settled certain accrued bonus amounts, through the issuance of stock options to certain employees, in lieu of cash bonuses.

For the three months ended September 30, 2024 and 2023, the amount of stock-based compensation expense included within research and development and general and administrative expenses was as follows:

	Three months ended, September 30,	
	2024	2023
Research and development	$ 173,475	$ 193,299
General and administrative	174,581	157,111
Total stock-based compensation expense	$ 348,056	$ 350,410

For the nine months ended September 30, 2024 and 2023, the amount of stock-based compensation expense included within research and development and general and administrative expenses was as follows:

	Nine months ended, September 30,	
	2024	2023
Research and development	$ 553,255	$ 1,227,166
General and administrative	522,870	1,795,590
Total stock-based compensation expense	$ 1,076,125	$ 3,022,756

6. COMMITMENTS AND CONTINGENCIES

Clinical trials

Since 2010, the Company has entered into multiple clinical trial agreements with medical institutions in the United States, Europe and Asia for the purpose of enrolling patients into various clinical trials. The agreements are substantially similar by trial and include a detailed listing of the clinical trial services for which the Company will pay, how much will be paid for each service, a set-up charge (if any), Investigational Review Board fees, contractual term, and other provisions. The clinical trial services provided by each site generally include the screening of prospective patients and, for those patients to be enrolled in the study, administration of the Company's investigation drug according to the trial protocol, any required hospitalization, ancillary medical supplies, and 2-week patient follow-up. Further, each agreement requires the Company to indemnify each respective clinical site against any and all liability, loss, or damage it may suffer as a result of third-party claims; the Company maintains product liability insurance in conjunction with this indemnification. The agreements may be terminated upon 30 days' written notice, subject to conditions of paying all liabilities incurred through the date of termination. Additionally, with each screened patient, the Company incurs expense with other entities engaged to provide independent review of patient medical records.

As part of the Company's agreement with one of its clinical research organizations, the Company is required to maintain a 7% upfront float for fees related to expenses incurred in clinical studies. When the float has depleted to 15% (i.e. 85% of the float has been used) the Company will receive an invoice to replenish the float up to 7% of the remaining estimated budget for the studies. As of December 31, 2023 and September 30, 2024, the Company had no remaining prepaid float balance.

Indemnification

From time to time, in its normal course of business, the Company may indemnify other parties, with whom it enters into contractual relationships, including lessors and parties to other transactions with the Company. The Company may agree to hold other parties harmless against specific losses, such as those that could arise from a breach of representation, covenant or third-party infringement claims. It may not be possible to determine the maximum potential amount of liability under such indemnification obligations due to the unique facts and circumstances that are likely to be involved in each particular claim and indemnification provision. Historically, there have been no such indemnification claims. The Company has also indemnified its directors and executive officers, to the extent legally permissible, against all liabilities reasonably incurred in connection with any action in which such individual may be involved by reason of such individual being or having been a director or executive officer.

Operating Leases

During the period covered by these condensed consolidated financial statements, the Company had two leases. The first was a twelve-month lease on its former corporate office located at 19925 Stevens Creek Blvd., Suite 100, Cupertino, CA 95014. The monthly lease payment was approximately $1,447 and the lease was renewed in February 2022 and again on February 1, 2023, for another 12-month term. This lease terminated on January 31, 2024. The second lease was for a new corporate office located at 10080 N. Wolfe Road, Suite SW3-200, Cupertino, CA 95014. The monthly lease payment was approximately $4,300 and the lease was entered into beginning December 1, 2023 for a 12-month term. The operating lease cost on these leases for the three months ended September 30, 2024 and 2023 was approximately $12,896 and $5,155, respectively. The operating lease cost on these leases for the nine months ended September 30, 2024 and 2023 was approximately $37,231 and $15,355, respectively.

Litigation

The Company is not currently a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

7. FAIR VALUE MEASUREMENTS

The following tables provide a summary of the assets and liabilities that are required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of September 30, 2024 and December 31, 2023:

	September 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (cash equivalents)	$ 4,194,957	$ —	$ —	$ 4,194,957
Total assets measured and recorded at fair value	$ 4,194,957	$ —	$ —	$ 4,194,957
Liabilities:				
Warrant liabilities	$ —	$ —	$ 77,884	$ 77,884
Total liabilities measured and recorded at fair value	$ —	$ —	$ 77,884	$ 77,884

	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (cash equivalents)	$ 22,211,820	$ —	$ —	$ 22,211,820
Total assets measured and recorded at fair value	$ 22,211,820	$ —	$ —	$ 22,211,820
Liabilities:				
Warrant liabilities	$ —	$ —	$ 806,655	$ 806,655
Total liabilities measured and recorded at fair value	$ —	$ —	$ 806,655	$ 806,655

The following table summarizes the changes in the fair value of the warrant liabilities measured at fair value on a recurring basis using significant unobservable inputs (Level 3):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Balance, beginning of period	$ 150,205	$ 1,012,490	$ 806,655	$ 567,439
Change in fair value of warrant liabilities	(72,321)	(139,079)	(728,771)	305,972
Balance, end of period	$ 77,884	$ 873,411	$ 77,884	$ 873,411

In prior years, the Company issued warrants to purchase 556,313 shares of common stock in a private placement (the "Private Warrants") and classified the warrants as derivative liabilities, pursuant to ASC 815, as the Private Warrants have an exercise price that is subject to potential adjustment, with subsequent changes in their fair values to be recognized in the condensed consolidated statement of operations at each reporting date. The Company calculated the fair value of the Private Warrants as of September 30, 2024 and December 31, 2023 as $77,884 and $806,655, respectively, using a Lattice model. The key inputs used in the Lattice calculation were the following:

	September 30, 2024	December 31, 2023
Risk-free interest rate	3.91%	4.25%
Remaining expected term of Private warrants	1.21	1.96
Expected volatility (1)	123.60%	89.00%
Stock price on valuation date	$ 1.44	$ 5.15
Exercise price	$ 11.50	$ 11.50
Expected dividend rate	—%	—%

(1) Based on volatility implied by guideline company publicly traded warrant market prices.

8. SUBSEQUENT EVENTS

Grant of Employee Option Awards

On October 30, 2024, the Compensation Committee of the Board of Directors of the Company approved the grant of certain nonqualified stock options, under the Company's 2020 Equity Incentive Plan, to certain non-executive employees of the Company. A total of 730,000 options were approved, with a grant date of October 30, 2024. All options had an exercise price of $1.16, being the closing share price of the Company on the grant date, a term of five years, expiring on October 29, 2034, and will vest over periods ranging from sixteen months, to thirty-eight months.

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

The information in this Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") should be read in conjunction with the Company's unaudited condensed consolidated financial statements and the related notes set forth in Item 1 of Part I of this Quarterly Report on Form 10-Q, our MD&A set forth in Item 7 of Part II of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and the Company's consolidated financial statements and related notes set forth in Item 8 of Part II of such Annual Report on Form 10-K. See Part II, Item 1A, "Risk Factors," below and "Cautionary Note Regarding Forward-Looking Statements," below, and the information referenced therein, for a description of risks that we face and important factors that we believe could cause actual results to differ materially from those in our forward-looking statements. All amounts and percentages are approximate due to rounding and all dollars in the text are in millions, except per share amounts or where otherwise noted. When we cross-reference to a "Note," we are referring to our "Notes to Condensed Consolidated Financial Statements (Unaudited)" included in Part I, Item 1, of this Quarterly Report on Form 10-Q, unless the context indicates otherwise.

All statements other than statements of historical fact included in this section regarding our financial position, business strategy and the plans and objectives of management for future operations, are forward-looking statements. When used in this section, words such as "anticipate," "believe," "estimate," "expect," "intend" and similar expressions, as they relate to our management, identify forward-looking statements. Such forward-looking statements are based on the beliefs of management, as well as assumptions made by, and information currently available to, our management. Actual results could differ materially from those contemplated by the forward- looking statements as a result of certain factors detailed herein. All subsequent written or oral forward-looking statements attributable to us or persons acting on our behalf are qualified in their entirety by this paragraph.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 under Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include statements with respect to our beliefs, plans, objectives, goals, expectations, anticipations, assumptions, estimates, intentions and future performance, and involve known and unknown risks, uncertainties and other factors, which may be beyond our control, and which may cause our actual results, performance or achievements to be materially different from future results, performance or achievements expressed or implied by such forward-looking statements. All statements other than statements of historical fact are statements that could be forward-looking statements. You can identify these forward-looking statements through our use of words such as "may," "can," "anticipate," "assume," "should," "indicate," "would," "believe," "contemplate," "expect," "seek," "estimate," "continue," "plan," "point to," "project," "predict," "could," "intend," "target," "potential" and other similar words and expressions of the future.

There are a number of important factors that could cause the actual results to differ materially from those expressed in any forward-looking statement made by us. These factors include, but are not limited to:

- the success of our current or planned clinical trials through all phases of clinical development, including our ability to conduct and complete clinical trials in accordance with projected timelines, our ability to achieve the desired results, and our ability to successfully complete requisite regulatory review and approval processes;
- our ability to obtain the necessary financing to continue to conduct our business operations as planned, and to conduct our ongoing and planned trials, and continue and complete the planned development and commercialization of our product candidates;
- expectations regarding our ability to continue as a going concern;
- our ability to grow and manage growth economically;
- our ability to retain key executives and medical and science personnel;
- the possibility that our products in development succeed in or fail clinical trials or are not approved by the U.S. Food & Drug Administration ("FDA") or other applicable authorities;
- the possibility that we could be forced to delay, reduce or eliminate our planned clinical trials or development programs;
- our ability to obtain approval from regulatory agents in different jurisdictions for our current or future product candidates;
- changes in applicable laws or regulations;
- changes to our relationships within the pharmaceutical ecosystem;
- the performance of third-party suppliers and manufacturers and our ability to find additional suppliers and manufacturers and obtain alternative sources of raw materials;
- our current and future capital requirements to support our development and commercialization efforts and our ability to satisfy our capital needs;
- our ability to access capital on acceptable terms in a rising interest rate and tighter credit environment;
- the accuracy of our estimates regarding expenses and capital requirements, including estimated costs of our clinical studies;
- our limited operating history;
- our history of operating losses in each year since inception and expectation that we will continue to incur operating losses for the foreseeable future;
- the valuation of our private common warrants could increase the volatility in our net income (loss);
- changes in the markets that we target;

- our ability to maintain or protect the validity of our patents and other intellectual property;
- our exposure to any liability, protracted and costly litigation or reputational damage relating to data security;
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements;
- the commercial, reputational and regulatory risks to our business that may arise as a consequence of our previously-disclosed restatement of our financial statements;
- any disruption to our business that may occur on a longer-term basis should we be unable to remediate the material weaknesses we have identified in our internal controls over financial reporting and clinical trial expenses;
- our ability to develop and maintain effective internal controls;
- our ability to maintain the listing of our common stock and listed warrants on Nasdaq; and
- the possibility that we may be adversely affected by other economic, business, and/or competitive factors.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in such forward-looking statements. Please see "Part II-Item 1A-Risk Factors" for additional risks which could adversely impact our business and financial performance.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this report or the date of the document incorporated by reference into this report. We have no obligation, and expressly disclaims any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise. We have expressed our expectations, beliefs and projections in good faith and believe they have a reasonable basis. However, we cannot assure you that our expectations, beliefs or projections will result or be achieved or accomplished.

Company Overview

We are a late-stage pharmaceutical company that discovers, develops, and seeks to commercialize next-generation therapeutics for diseases representing significant unmet medical needs and burdens to society, patients, and their families. Our current pipeline focuses on the central nervous system, inflammatory, and cardiometabolic diseases. We use a chemical genomics driven technology platform and proprietary chemistry to develop new medicines. Our pipeline currently has two drug candidates, brilaroxazine (RP5063) and RP1208. Both are new chemical entities discovered in-house. We have been granted composition of matter patents for both brilaroxazine and RP1208 in the United States (U.S.), Europe, and several other countries.

Our lead drug candidate, brilaroxazine, is in clinical development and is intended to treat multiple neuropsychiatric indications. These include schizophrenia, bipolar disorder ("BD"), major depressive disorder ("MDD"), attention-deficit/hyperactivity disorder ("ADHD"), behavioral and psychotic symptoms of dementia and Alzheimer's disease ("BPSD"), and Parkinson's disease psychosis ("PDP"). Furthermore, brilaroxazine is also ready for clinical development for two respiratory indications-pulmonary arterial hypertension ("PAH") and idiopathic pulmonary fibrosis ("IPF"). The U.S. Food and Drug Administration (the "FDA") granted Orphan Drug Designation to brilaroxazine for the treatment of PAH in November 2016 and IPF in April 2018. Brilaroxazine also is in preclinical development for the treatment of psoriasis.

Our primary focus is to complete the clinical development of brilaroxazine for the treatment of acute and maintenance schizophrenia.

On October 30, 2023, we announced positive topline results from our Phase 3 RECOVER 1 trial (the "RECOVER-1 Trial"), which is a global Phase 3, randomized, double-blind, placebo-controlled, multicenter study designed to assess the safety and efficacy of brilaroxazine in approximately 400 patients with acute schizophrenia compared to placebo. See "Recent Developments" below for more details on brilaroxazine development.

Subject to the receipt of additional financing, we may also continue the clinical development of brilaroxazine for the treatment of BD, MDD, ADHD, BPSD, PDP, PAH and IPF. Moreover, subject to the receipt of additional financing, we may also advance the development of our second drug candidate, RP1208, for the treatment of depression and obesity.

Recent Developments

On October 30, 2023, we announced positive topline results and successful completion of our pivotal RECOVER-1 Trial evaluating the efficacy, safety and tolerability of once-daily brilaroxazine, a serotonin dopamine signaling modulator in adults with schizophrenia. The trial successfully met its primary endpoint at the 50 mg dose, with brilaroxazine at that dose achieving a statistically significant and clinically meaningful 10.1-point reduction in Positive and Negative Syndrome Scale (PANSS) total score compared to placebo (-23.9 brilaroxazine 50 mg vs. -13.8 placebo, $p<0.001$) at week 4. Brilaroxazine also achieved statistically significant and clinically meaningful reductions in all major symptom domains and secondary endpoints at week 4 with the 50 mg dose vs. placebo. The 15 mg dose of brilaroxazine was numerically superior to placebo on the primary endpoint and most secondary endpoints, and reached statistical significance on two key secondary endpoints.

Key statistically significant and clinically meaningful improvements with brilaroxazine vs. placebo in patients with schizophrenia and a mean PANSS total score of 97-99 at baseline include:

Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
PANSS Total Score	10.1	*0.6*	*<0.001*
Positive Symptoms	2.8	*0.5*	*<0.001*
Negative Symptoms ("NS")	2.0	*0.4*	*0.003*
NS Marder Factor	2.1	*0.4*	*0.002*
PANSS Social Cognition	1.6	*0.5*	*<0.001*
PANSS Excitement/Agitation	2.1	*0.5*	*<0.001*
Personal and Social Performance	6.3	*0.5*	*<0.001*
CGI-S score	≥1	*0.5*	*<0.001*

Key clinical safety and tolerability findings of brilaroxazine support a well-tolerated safety profile

- No drug related serious adverse events (SAEs) or treatment-emergent SAEs (TESAEs) observed or major safety concerns reported for brilaroxazine after 4 weeks of treatment;
- No incidence of suicidal ideation;
- No significant change in bodyweight and blood glucose levels;
- Significant decrease in cholesterol, LDL and increase in HDL compared to placebo;
- Significant decrease in prolactin and no change in thyroid levels compared to placebo;
- Akathisia and extrapyramidal symptoms <1% reported for brilaroxazine 50 mg and none for 15 mg;
- Common brilaroxazine treatment-emergent adverse events (TEAEs) were headache (<6%) and somnolence (<7.5%) generally transient in nature; and
- Low discontinuation rates with brilaroxazine that were less than placebo (16% in brilaroxazine 50mg and 19% in brilaroxazine 15mg vs. 22% placebo).

The clinical development plan for brilaroxazine also includes the completed positive Phase 2 REFRESH trial, an ongoing 1-year open label extension trial evaluating long-term safety and tolerability (the "OLE Trial"), and a soon to be initiated registrational global, randomized 4-week Phase 3 RECOVER-2 trial (the "RECOVER-2 Trial"). We expect to report topline data from our OLE Trial in December 2024, with the OLE Trial expected to complete in Q-1 2025, and we expect to initiate the registrational RECOVER-2 Trial in the first quarter of 2025, subject to receipt of additional financing, with completion anticipated in the first quarter of 2026. RECOVER-2 was originally designed as a 6-week study, but after discussion between Reviva and the FDA, the agency has agreed that it can be conducted as a 4-week study. In addition, the FDA indicated that it will require a long-term randomized withdrawal study post-approval to support maintenance of effect. Data from these brilaroxazine clinical trials will potentially support the planned NDA submission to the FDA in the second quarter of 2026.

Open Label Extension (OLE) Trial Enrollment Update

In November 2024, we provided the following enrollment update on our ongoing OLE Trial evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia.

- Global trial progressing well;
- 108 patients have completed 1-year (12-month) of treatment;
- Over 250 patients have completed 6-months of treatment;
- Blood and digital biomarkers designed to independently support efficacy
- Long-term safety data from 100 patients who have completed 12 months of treatment is a requirement for brilaroxazine's NDA submission to the FDA; and
- 12 month long-term study expected to complete in Q1 2025.

May 2024 Registered Direct Offering

On May 28, 2024, we entered into a securities purchase agreement (the "Purchase Agreement"), pursuant to which we issued and sold an aggregate of 1,898,734 shares of our common stock and warrants to purchase up to 1,898,734 shares of our common stock (the "May 2024 Warrants") at a combined offering price of $1.58 per share of common stock and accompanying May 2024 Warrant in a registered direct offering ("May 2024 Offering"). The May 2024 Warrants have an exercise price of $1.455 per share, are immediately exercisable and expire five years following the date of issuance. The net proceeds to the Company from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by the Company, of $0.4 million. On May 29, 2024, we closed the May 2024 Offering.

In connection with the May 2024 Offering, we also agreed to amend certain existing warrants held by the investor in the May 2024 Offering to purchase up to an aggregate of 1,365,854 shares of our common stock that were previously issued to the investor in November 2023, with an exercise price of $5.00 per share, for $0.125 per amended warrant, so that the amended warrants have a reduced exercise price of $1.455 per share and expire five years following the closing of the May 2024 Offering.

August 2024 Underwritten Offering

On August 20, 2024, we entered into an underwriting agreement (the "Underwriting Agreement") with Titan Partners Group LLC, a division of American Capital Partners, LLC, as the underwriter, relating to the offering, issuance and sale of (i) 3,276,262 shares of common stock, (ii) pre-funded warrants (the "August 2024 Pre-Funded Warrants") exercisable for an aggregate of up to 1,485,643 shares of common stock, and (iii) warrants (the "August 2024 Warrants") exercisable for an aggregate of 4,761,905 shares of common stock (the "August 2024 Offering"). The public offering price for each share of common stock and accompanying August 2024 Warrant to purchase one share of common stock (including the pricing for the warrant repricing described below) was $1.05, and the public offering price for each August 2024 Pre-Funded Warrant and accompanying August 2024 Warrant to purchase one share of common stock was $1.0499. The net proceeds to the Company from the August 2024 Offering were approximately $3.7 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The August 2024 Offering closed on August 22, 2024

Upon the closing of the August 2024 Offering, we issued to the Underwriter warrants to purchase up to 238,095 shares of common stock (the "August 2024 Underwriter Warrants"). The August 2024 Underwriter Warrants will be exercisable at an exercise price of $1.3125 per share and are exercisable during the five-year period commencing six months after the closing date of the August 2024 Offering.

In connection with the August 2024 Offering, on August 20, 2024, the Company entered into a warrant amendment agreement (the "August 2024 Warrant Amendment Agreement") with the purchaser of the August 2024 Pre-Funded Warrants pursuant to which the Company agreed to amend the purchaser's (i) warrants to purchase up to 2,536,586 shares of common stock at an exercise price of $5.00 per share issued in November of 2023 and (ii) warrants to purchase up to 2,199,975 shares of common stock at an exercise price of $4.125 per share issued in June of 2021 (together, the "August 2024 Existing Warrants"), in consideration for such investor's participation in the August 2024 Offering and the payment of $0.125 per August 2024 Existing Warrant (which amount is included in the $1.05 offering price above) to (i) lower the exercise price of the August 2024 Existing Warrants to $0.7964 per share and (ii) amend the expiration date of the August 2024 Existing Warrants to five years following the closing of the August 2024 Offering.

Financial Overview

We have incurred losses since inception and as of September 30, 2024 we had a working capital deficit of approximately $10.7 million, an accumulated deficit of $158.0 million and cash and cash equivalents on hand of approximately $5.6 million. Our net loss for the three months ended September 30, 2024 and 2023, was approximately $8.4 million and $11.3 million, respectively. Our net loss for the for the nine months ended September 30, 2024 and 2023, was approximately $23.7 million and $29.9 million, respectively. We expect to incur significant expenses and increased operating losses for the next several years. We expect our expenses to increase in connection with our ongoing activities to research, develop and commercialize our potential product candidates. We will need to generate significant revenues to achieve profitability, and we may never do so.

We expect our expenses will increase substantially in connection with our ongoing activities, as we:

- invest significantly to further research and develop, through clinical trials for brilaroxazine including the OLE Trial and the registrational RECOVER-2 Trial, and pre-clinical research for RP1208, and seek regulatory approval for our product candidates brilaroxazine and RP1208;
- identify and develop additional product candidates;
- hire additional clinical, scientific and management personnel;
- seek regulatory and marketing approvals for any product candidates that we may develop;

- ultimately establish a sales, marketing and distribution infrastructure to commercialize any drugs for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other drugs and technologies; and
- add operational, financial and management information systems and personnel, including personnel to support our product candidate development, and any future commercialization efforts, and our ongoing compliance with and maintenance of public company controls, procedures and regulatory requirements and standards.

Research and Development Expenses

We focus our resources on research and development activities, including the conduct of preclinical and clinical studies and product development and expense such costs as they are incurred. We have not historically tracked or recorded research and development expenses on a project-by-project basis, primarily because we use our employee and infrastructure resources across multiple research and development projects, and it is not practical for us to allocate such costs on a project-by-project basis. Our research and development expenses primarily consist of clinical trial expenses and employee-related expenses, including deferred salaries, salaries, benefits and taxes for personnel in research and development functions.

The largest recurring component of our total operating expenses has historically been research and development activities. We expect our research and development expenses will increase for the next several years as we advance our development programs, pursue regulatory approval of our product candidates in the U.S. and other jurisdictions and prepare for potential commercialization, which would require a significant investment in costs related to contract manufacturing and inventory buildup.

Our primary product candidates and their current status is as follows:

Drug Candidate	Indication	Status
Brilaroxazine (RP5063)	Schizophrenia	-Conducted pivotal Phase 3 RECOVER-1 and long-term safety studies. Topline data for the RECOVER-1 Trial announced October 30, 2023 -OLE Trial topline data readout expected in December 2024, with OLE Trial expected to complete in Q1-2025 -Registrational Phase 3 RECOVER-2 Trial expected initiation in Q1-2025, subject to receipt of additional financing, with completion anticipated in Q1-2026
Brilaroxazine	Bipolar Disorder	Phase 1 complete**
Brilaroxazine	Depression-MDD	Phase 1 complete**
Brilaroxazine	Alzheimer's (AD-Psychosis/Behavior)	Phase 1 complete**
Brilaroxazine	Parkinson's	Phase 1 complete**
Brilaroxazine	ADHD/ADD	Phase 1 complete**
Brilaroxazine	PAH	Phase 1 complete**
Brilaroxazine	IPF	Phase 1 complete**
Brilaroxazine	Psoriasis	In pre-clinical development
RP1208	Depression	Completed pre-clinical development studies, including in vitro receptor binding studies, animal efficacy studies, and PK studies. Compound ready for IND enabling studies.
RP1208	Obesity	Completed pre-clinical development studies, including in vitro receptor binding studies and PK studies. Compound ready for animal efficacy studies.

** We completed the Phase 1 clinical study for brilaroxazine prior to starting the Phase 2 study in schizophrenia and schizoaffective disorder, and completed our RECOVER-1 Trial for which we announced topline data in October 2023. In these three studies, we collected safety data for brilaroxazine in over 800 patients, including healthy subjects and patients with stable schizophrenia, acute schizophrenia and schizoaffective disorder. Generally, no separate Phase 1 study is required for conducting a Phase 2 study for an additional indication, provided the treatment doses in the Phase 2 study for an additional indication are within the range of doses tested in the previously completed Phase 1 study.

The successful development of our platform and product candidates is highly uncertain, and we may never succeed in achieving marketing approval for our product candidates brilaroxazine (RP5063), RP1208, or any future product candidates. In connection with the activities required to complete the development of brilaroxazine for schizophrenia, including our ongoing OLE Trial and our planned registrational RECOVER-2 Trial, we expect to incur substantial additional costs over the 2024-2026 period to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. We expect our clinical costs in connection with the development of brilaroxazine for schizophrenia may total approximately $70 million over the next approximately three years, consisting of our estimated costs for (i) completion of our OLE Trial, (ii) our RECOVER-2 Trial through the planned NDA submission, and (iii) additional Research & Development costs (primarily associated with consulting, scientific, research and other expenses in support of the OLE and RECOVER-2 Trials through the planned NDA as well as certain activities in preparation of potential commercialization if the product attains approval). The foregoing forecasted amount of expenses is an estimate based on numerous factors and information available to management as of today, and is subject to change. The actual amount of such expenses could be materially higher or lower than the forecasted amount. The foregoing statements regarding estimates of forecasted future costs and expenses represent forward-looking statements. See "Cautionary Note Regarding Forward-Looking Statements." At this time, other than providing reasonable estimates and forecasts based on information available to us of what we expect future costs may be in connection with the RECOVER-2 and OLE Trials and certain associated expenses and other future activities needed to continue to develop brilaroxazine, we cannot reasonably estimate the nature, timing, or costs of the efforts necessary to finish developing any of our product candidates or the period in which material net cash, if any, from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing therapeutics, including the uncertainty of:

- the scope, rate of progress, expense, and results of clinical trials;

- the scope, rate of progress, and expense of process development and manufacturing;
- preclinical and other research activities; and
- the timing of regulatory approvals.

General Administrative Expenses

General and administrative expenses primarily consist of payroll and related costs for employees in executive, business development, finance, and administrative functions. Other significant general and administrative expenses include professional fees for accounting and legal services.

We expect general and administrative expenses to increase as we expand infrastructure and continue the development of our clinical programs. Other increases could potentially include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel, and increased fees for directors, outside consultants, lawyers, and accountants. We expect to incur significant costs to comply with corporate governance, internal controls, and similar requirements applicable to public companies.

Critical Accounting Estimates

Our critical accounting estimates are disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed with the SEC on April 15, 2024. Since the date of the Annual Report, there have been no material changes in our critical accounting estimates.

Previously-Disclosed Restatement of Previously Reported Interim Condensed Consolidated Quarterly Financial Statements

The interim consolidated financial statements include corrections to the three and nine months ended September 30, 2023, which corrections were previously presented in the audited consolidated financial statements and notes thereto, including specifically Note 10, "*Quarterly Financial Data (Unaudited and Restated)*", for the fiscal year ended December 31, 2023, included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC on April 15, 2024 (sometimes hereinafter referred to as the "2023 Form 10-K").

As previously reported in Item 4.02(a) of our Current Report on Form 8-K as filed with the SEC on April 15, 2024, and in our 2023 Form 10-K, on April 12, 2024, we concluded that our previously issued financial statements for the Restatement Periods should be restated to correct historical errors related principally to the timing of recognition of our estimated accrual of certain research and development ("R&D") expenses from a contract research organization, specifically investigator fees, were recorded as R&D expenses during the year ended December 31, 2022 and throughout the year ended December 31, 2023 when the underlying invoices were received, rather than when the services (i.e. patient visit and enrollment ("Patient Visit Date")) were provided. In addition, we determined that an effective process for evaluating the completeness of the R&D accrual for the investigator fees was necessary. This included determining an estimate for accruals based on estimated patient site visits not yet reported, average site visits costs and average delay in site invoicing. This provides us with an accurate estimate of the costs incurred as there can be a lag between receiving an invoice for the services provided.

Therefore, as previously disclosed, we misstated R&D expenses and associated accrued liabilities for the fiscal year ended December 31, 2022 included in our Annual Report on Form 10-K, the interim financial statements for the quarterly period ended September 30, 2022 included in our Quarterly Report on Form 10-Q, and each of the interim financial statements for the quarterly periods in fiscal 2023 included in our Quarterly Reports on Form 10-Q (cumulatively, the "Restatement Periods"). Also as previously disclosed, we principally attribute the errors to (i) a material weakness in internal control activities due to a failure in the design and implementation of our controls to review clinical trial expenses, including the evaluation of the terms of clinical trial contracts, specifically, we failed to properly review and evaluate progress of expenses incurred in clinical trial contracts resulting in us not properly accruing for clinical trial expenses that were incurred but for which invoices were not yet received, and (ii) a material weakness in internal controls due to insufficient resources including in relation to our financial close and reporting process with appropriate knowledge and expertise to design, implement, document and operate effective internal controls over financial reporting. This material weakness has a pervasive impact and consequently, impacts control activities over all financial statement account balances, classes of transactions, and disclosure. These material weaknesses were previously disclosed in Item II, Part 9A of our 2023 Form 10-K, and are disclosed in Part I, Item 4 of this Quarterly Report on Form 10-Q. We have commenced procedures to remediate the material weaknesses. However, these material weaknesses will not be considered remediated until the applicable remedial actions have been fully implemented and we have concluded that these controls are operating effectively for a sufficient period of time.

The discussion of financial results presented here is reflective of the foregoing adjustments.

Results of Operations

Comparison of the three months ended September 30, 2024 and 2023:

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Change Amount	Change Percentage
	2024	2023 (as restated)		
Operating expenses				
Research and development	$ 6,858,285	$ 9,572,180	$ (2,713,895)	(28.4)%
General and administrative	1,604,249	1,991,774	(387,525)	(19.5)%
Total operating expenses	8,462,534	11,563,954		
Loss from operations	(8,462,534)	(11,563,954)		
Gain on remeasurement of warrant liabilities	72,321	139,079	(66,758)	(48.0)%
Interest expense	(5,146)	(5,901)	755	(12.8)%
Interest income	53,248	91,763	(38,615)	(42.1)%
Other income (expense), net	(23,687)	5,194	(28,881)	(556.0)%
Total other income, net	96,736	230,135		
Loss before provision for income taxes	(8,365,798)	(11,333,819)		
Provision for income taxes	—	12,117	(12,117)	(100.0)%
Net loss	$ (8,365,798)	$ (11,345,936)		

Research and Development Expenses

Research and development costs are expensed as incurred. These expenses represent both internal and external costs.

For the three months ended September 30, 2024 and 2023, research and development expenses were approximately $6.9 million and $9.6 million, respectively. Specifically, during the three months ended September 30, 2024 and 2023, our research and development costs consisted primarily of the following costs associated with our key research and development project for advancing the clinical development of brilaroxazine during the reporting periods, namely our OLE and RECOVER-1 Trials for our Phase 3 clinical study for brilaroxazine: (i) internal salaries, wages and other payroll related costs for employees involved in research and development activities, of approximately $0.4 million and $0.8 million, respectively; (ii) internal share-based compensation expenses with respect to employees involved in research and development activities, of approximately $0.3 million and $0.2 million, respectively; (iii) other research and development related costs, of an insignificant amount in each period; and (iv) external research and development expenses, of approximately $6.2 million and $8.5 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately $5.6 million and $7.3 million, respectively, non-clinical safety related costs of approximately $0.4 million and $0.4 million, respectively, non-clinical manufacturing related costs of approximately $0.2 million and $0.7 million, respectively, and non-clinical consulting and other related costs of an insignificant amount and approximately $0.1 million, respectively).

The decrease in research and development expenses for the three months ended September 30, 2024, as compared to the three months ended September 30, 2023, was primarily attributed to a decrease in external research and development costs, including clinical consulting, due to completion of the RECOVER-1 Trial on October 31, 2023, offset by additional external research and development costs related to a change order entered into on September 25, 2024, which increased the scope of certain services provided by a clinical research organization.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with our ongoing operations, including expenses associated with activities required to complete the development of brilaroxazine in schizophrenia including our planned registrational RECOVER-2 Trial, to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. For additional information, please see the discussion appearing above in the introductory section of this Part I-Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, of this Quarterly Report on Form 10-Q, under the caption "*Financial Overview–Research and Development Expenses*".

General and Administrative Expenses

For the three months ended September 30, 2024 and 2023, general and administrative expenses were approximately $1.6 million and $2.0 million, respectively. Specifically, during the three months ended September 30, 2024 and 2023, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately $0.2 million and $0.2 million, respectively; (ii) consultant and professional expenses of approximately $0.6 million and $0.5 million, respectively; (iii) legal expenses of approximately $0.2 million and $0.3 million, respectively; (iv) employee related expenses of approximately $0.4 million and $0.6 million, respectively; and (v) other general and administrative expenses of approximately $0.2 million and $0.4 million, respectively.

Gain on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities gain of approximately $72.3 thousand and $139.1 thousand for the three months ended September 30, 2024 and 2023, respectively. The approximate $72.3 thousand gain on remeasurement of warrant liabilities for the three months ended September 30, 2024 resulted from the decrease in the calculated fair value of the warrants, principally as a result of the decrease in our stock price during the three months ended September 30, 2024. The approximate $139.1 thousand gain on remeasurement of warrant liabilities for the three months ended September 30, 2023 resulted from the decrease in the calculated fair value of the warrants, principally as a result of the decrease in our stock price during the three months ended September 30, 2023.

Interest Expense

We incurred interest expense of approximately $5.1 thousand and $5.9 thousand for the three months ended September 30, 2024 and 2023, respectively. The approximate $0.8 thousand decrease in interest expense was primarily caused by a decrease in the corresponding short-term debt balance for the period.

Interest Income

Interest income was approximately $53.2 thousand and $91.8 thousand for the three months ended September 30, 2024 and 2023, respectively. While there has been an increase in market interest rates in 2024 compared to 2023, interest income decreased approximately $38.6 thousand primarily due to us maintaining a lower cash balance throughout the current year period, as compared to the prior year period.

Other Income (Expense), Net

Other expense, net incurred was approximately $23.7 thousand for the three months ended September 30, 2024 and other income, net incurred was approximately $5.2 thousand for the three months ended September 30, 2023. The change from income to an expense was approximately $28.9 thousand and was primarily attributable to an unrealized foreign currency translation loss from negative foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Comparison of the nine months ended September 30, 2024 and 2023:

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023:

	Nine Months Ended September 30,		Change Amount	Change Percentage
	2024	2023 (as restated)		
Operating expenses				
Research and development	$ 18,226,497	$ 23,312,661	$ (5,086,164)	(21.8)%
General and administrative	6,287,786	6,571,629	(283,843)	(4.3)%
Total operating expenses	24,514,283	29,884,290		
Loss from operations	(24,514,283)	(29,884,290)		
Gain (loss) on remeasurement of warrant liabilities	728,771	(305,972)	1,034,743	(338.2)%
Interest expense	(13,786)	(20,414)	6,628	(32.5)%
Interest income	313,956	341,854	(27,898)	(8.2)%
Other income (expense), net	(159,202)	(15,220)	(143,982)	946.0%
Total other income, net	869,739	248		
Loss before provision for income taxes	(23,644,544)	(29,884,042)		
Provision for income taxes	14,781	21,531	(6,750)	(31.4)%
Net loss	$ (23,659,325)	$ (29,905,573)		

Research and Development Expenses

Research and development costs are expensed as incurred. These expenses represent both internal and external costs.

For the nine months ended September 30, 2024 and 2023, research and development expenses were approximately $18.2 million and $23.3 million, respectively. Specifically, during the nine months ended September 30, 2024 and 2023, our research and development costs consisted primarily of the following costs associated with our key research and development project for advancing the clinical development of brilaroxazine during the reporting periods, namely our OLE and RECOVER-1 Trials for our Phase 3 clinical study for brilaroxazine: (i) internal salaries, wages and other payroll related costs for employees involved in research and development activities, of approximately $1.9 million and $2.2 million, respectively; (ii) internal share-based compensation expenses with respect to employees involved in research and development activities, of approximately $0.6 million and $1.2 million, respectively; (iii) other research and development related costs, of an insignificant amount and approximately $0.2 million, respectively; and (iv) external research and development expenses, of approximately $15.7 million and $19.7 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately $12.6 million and $16.5 million, respectively, non-clinical safety related costs of approximately $0.8 million and $1.7 million, respectively, non-clinical manufacturing related costs of approximately $2.0 million and $1.2 million, respectively, and non-clinical consulting and other related costs of approximately $0.3 million for both periods).

The decrease in research and development expenses for the nine months ended September 30, 2024 as compared to the nine months ended September 30, 2023 was primarily attributed to a decrease in external research and development costs, including clinical consulting, due to completion of the RECOVER-1 Trial on October 31, 2023, offset by additional external research and development costs related to a change order entered into on September 25, 2024 which increased the scope of certain services provided by a clinical research organization.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with our ongoing operations, including expenses associated with activities required to complete the development of brilaroxazine in schizophrenia including completion of our OLE Trial and our planned registrational RECOVER-2 Trial, to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. For additional information, please see the discussion appearing above in the introductory section of this Part I-Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations, of this Quarterly Report on Form 10-Q, under the caption "*Financial Overview–Research and Development Expenses*".

General and Administrative Expenses

For the nine months ended September 30, 2024 and 2023, general and administrative expenses were approximately $6.3 million and $6.6 million, respectively. Specifically, during the nine months ended September 30, 2024 and 2023, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately $0.5 million and $1.8 million, respectively; (ii) consultant and professional expenses of approximately $2.7 million and $1.3 million, respectively; (iii) legal expenses of approximately $1.0 million and $0.9 million, respectively; (iv) employee related expenses of approximately $1.4 million and $1.6 million, respectively; (v) D&O insurance expenses of 0.4 million approximately and $0.7 million, respectively, and (vi) other general and administrative expenses of approximately $0.3 for both periods.

Gain (Loss) on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities gain of approximately $728.8 thousand and a loss of $306.0 thousand for the nine months ended September 30, 2024 and 2023, respectively. The approximate $728.8 thousand gain on remeasurement of warrant liabilities for the nine months ended September 30, 2024 resulted from the decrease in the calculated fair value of the warrants, principally as a result of the decrease in our stock price during the nine months ended September 30, 2024. The approximate $306.0 thousand loss on remeasurement of warrant liabilities for the nine months ended September 30, 2023 resulted from the increase in the calculated fair value of the warrants, principally as a result of the increase in stock price during the nine months ended September 30, 2023.

Interest Expense

We incurred interest expense of approximately $13.8 thousand and $20.4 thousand for the nine months ended September 30, 2024 and 2023, respectively. The approximate $6.6 thousand decrease in interest expense was primarily caused by a decrease in the corresponding short-term debt balance for the period.

Interest Income

Interest income was approximately $314.0 thousand and $341.9 thousand for the nine months ended September 30, 2024 and 2023, respectively. Interest income slightly decreased by $27.9 thousand primarily due to the lower cash balance at the end of the nine month period compared to the prior period.

Other Expense, net

Other expense incurred was approximately $159.2 thousand and $15.2 thousand for the nine months ended September 30, 2024 and 2023, respectively. The approximate $144.0 thousand decrease in other expense was primarily attributable to an unrealized foreign currency translation loss from negative foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Liquidity and Capital Resources

	September 30, 2024	December 31, 2023	Change Amount	Change Percentage
Balance Sheet Data:				
Cash and cash equivalents	$ 5,558,817	$ 23,367,456	$ (17,808,639)	(76.2)%
Working capital (deficit)	(10,723,725)	6,525,371	(17,249,096)	(264.3)%
Total assets	7,629,872	23,700,388	(16,070,516)	(67.8)%
Total stockholders' equity (deficit)	(9,981,888)	5,718,716	(15,700,604)	(274.5)%

	Nine Months Ended September 30, 2024	2023	Change Amount	Change Percentage
Statement of Cash Flow Data:				
Net cash used in operating activities	$ (24,443,419)	$ (19,447,908)	$ (4,995,511)	25.7%
Net cash provided by financing activities	6,634,780	5,900,350	734,430	12.4%
Net decrease in cash and cash equivalents	$ (17,808,639)	$ (13,547,558)	$ (4,261,081)	31.5%

Capital Resources

We have funded our operations to date primarily from the issuance and sale of our equity and convertible equity securities. As of September 30, 2024 we had cash and cash equivalents of approximately $5.6 million. To fund our current operating plans, we will need to raise significant additional capital. Our existing cash and cash equivalents will not be sufficient for us to complete development of our product candidates and, if applicable, to prepare for commercializing any product candidate that may receive approval. Accordingly, we will continue to require substantial additional capital beyond our existing cash to continue our clinical development and potential commercialization activities. We believe that we have adequate cash on hand to cover anticipated outlays into the end of the fourth quarter of fiscal year 2024, but will need additional fundraising activities and cash on hand during the fourth quarter of fiscal year 2024. We have based this estimate, however, on assumptions that may prove to be wrong, and could spend available financial resources much faster than we currently expect. We will need to raise additional funds to continue funding our development efforts and operations. We intend to secure such additional funding, although there are no guarantees or commitments for additional funding. These conditions raise substantial doubt regarding our ability to continue as a going concern for a period of one year after the date the financial statements are issued. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our clinical development efforts. We will seek to fund our operations through public or private equity or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed would have a negative impact on our financial condition, and our ability to pursue our business strategy, and our ability to continue as a going concern. We cannot assure you that we will ever be profitable or generate positive cash flow from operating activities.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue our research and preclinical and clinical development of our product candidates; expand the scope of our current studies for our product candidates; initiate additional preclinical, clinical or other studies for our product candidates; change or add additional manufacturers or suppliers; seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical studies; seek to identify, evaluate and validate additional product candidates; acquire or in-license other product candidates and technologies; maintain, protect and expand our intellectual property portfolio; attract and retain skilled personnel; add operational, financial and management information systems and personnel, including personnel to support our product candidate development, and any future commercialization efforts, and our ongoing compliance with and maintenance of public company controls, procedures and regulatory requirements and standards, including in connection with our ongoing remediation efforts regarding the material weaknesses in our internal controls as disclosed in this Quarterly Report including in Part I, Item 4 hereof; and experience any delays or encounter issues with any of the above. See also the discussion set forth under the caption "Financial Overview" appearing in this Management's Discussion and Analysis of Financial Condition and Results of Operation section above.

In January 2024, we obtained financing for certain Director & Officer liability insurance policy premiums. The governing agreement assigns the lender a first priority lien on and security interest in the financed policies and any additional premium required in the financed policies. The total premiums, taxes, and fees financed was $519 thousand with an annual percentage interest rate of 7.99% and has a term of 12 months.

During the nine months ended September 30, 2024, there were 347,643 pre-funded warrants exercised at an exercise price of $0.0001 per warrant share.

On May 28, 2024, we entered into the Purchase Agreement, pursuant to which we sold, in the May 2024 Offering, priced at the market under Nasdaq rules, which closed on May 29, 2024, an aggregate of (i) 1,898,734 shares of our common stock, and (ii) the May 2024 Warrants, which are exercisable for an aggregate of up to 1,898,734 shares of our common stock. The public offering price for each share of our common stock and accompanying May 2024 Warrant to purchase one share of our common stock was $1.58. The May 2024 Warrants have a term of 5 years and expire on May 29, 2029. The net proceeds to us from the May 2024 Offering were $2.8 million, after deducting placement offering costs, agent fees and expenses and other offering expenses payable by us, of approximately $0.4 million.

On August 20, 2024, we entered into the Underwriting Agreement, pursuant to which we sold (i) 3,276,262 shares of our common stock, (ii) the August 2024 Pre-Funded Warrants exercisable for an aggregate of up to 1,485,643 shares of common Stock, and (iii) the August 2024 Warrants exercisable for an aggregate of 4,761,905 shares of common stock. The public offering price for each share of common stock and accompanying August 2024 Warrant to purchase one share of common stock (including the pricing for warrant repricing) was $1.05, and the public offering for each August 2024 Pre-Funded Warrant and accompanying August 2024 Warrant to purchase one share of common stock was $1.0499. The net proceeds to the Company from the August 2024 Offering were approximately $3.1 million, after deducting underwriting discounts and commissions and other offering expenses payable by the Company. The August 2024 Offering closed on August 22, 2024. Total issuance costs were approximately $1.4 million, which included the fair value of the underwriter warrants issued, of $0.2 million.

Until such time as we can generate substantial product revenue, if ever, we expect to finance our cash needs through a combination of equity or debt financings and collaboration agreements. We do not currently have any committed external sources of capital. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing stockholders. If we raise additional funds through collaboration agreements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of or eliminate one or more of our clinical trials or research and development programs or make changes to our operating plan, or curtail or cease operations. We will need to generate significant revenues to achieve profitability, and we may never do so.

Cash Flows

Net Cash Used in Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2024 was approximately $24.4 million, consisting primarily of a net loss of approximately $23.7 million, adjusted for non-cash items, including a change in fair value of warrant liabilities gain of approximately $0.7 million, and stock-based compensation expense of approximately $1.1 million, coupled with a change in our operating assets and liabilities totaling approximately $1.1 million. The $1.1 million change in net operating assets and liabilities was primarily due to a decrease in accrued clinical expenses and other accrued expenses coupled with an increase in prepaid clinical trial costs, and an increase in prepaid expenses and other current assets, offset by an increase in accounts payable and a decrease in accrued compensation.

Net cash used in operating activities for the nine months ended September 30, 2023, was approximately $19.4 million, consisting primarily of a net loss of approximately $29.9 million, adjusted for non-cash items, including a change in fair value of warrant liabilities loss of approximately $0.3 million, and stock-based compensation expense of approximately $3.0 million, coupled with a change in our operating assets and liabilities totaling approximately $7.1 million. The $7.1 million change in net operating assets and liabilities was primarily due to an increase in accounts payable coupled with an increase in accrued expenses and other current liabilities and prepaid expenses and other current assets.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was approximately $6.6 million. Cash provided by financing activities was attributable to approximately $6.6 million in proceeds from the issuance of common stock and warrants and from modification of existing warrants, net of issuance costs, proceeds from issuance of short-term debt of approximately $0.4 million which is offset by repayments on the short-term debt of approximately $0.3 million.

Net cash provided by financing activities for the nine months ended September 30, 2023 was approximately $5.9 million. Cash provided by financing activities was attributable to approximately $0.7 million in proceeds from the issuance of short-term debt and approximately $5.7 million in proceeds from the exercise of warrants for common stock, slightly offset by the repayments of short-term debt of approximately $0.4 million.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company, we are not required to provide the information called for by this item.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of September 30, 2024. Based on such evaluation, as a result of the material weaknesses in internal control over financial reporting and clinical trial expenses described below, our principal executive officer and principal financial officer have concluded that, as of September 30, 2024, our disclosure controls and procedures were not effective at the reasonable assurance level.

There is a material weakness in our internal control activities due to a failure in the design and implementation of our controls to review clinical trial expenses, including the evaluation of the terms of clinical trial contracts. Specifically, we failed to properly review and evaluate progress of expenses incurred in clinical trial contracts resulting in us not properly accruing for clinical trial expenses that were incurred but for which invoices were not yet received. In addition, there is a material weakness in our internal control environment over financial reporting due to insufficient resources including in relation to our financial close and reporting process with appropriate knowledge and expertise to design, implement, document and operate effective internal controls over financial reporting. This material weakness has a pervasive impact and consequently, impacts control activities over all financial statement account balances, classes of transactions, and disclosure.

We are committed to continuing to improve our internal control over financial reporting and the review of our clinical trial expenses. As of the date hereof, we have commenced procedures to remediate the material weaknesses. We will continue to monitor the design and effectiveness of these procedures and controls and make any further changes we determine appropriate.

Notwithstanding the existence of the material weaknesses as described above, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations, and cash flow as of the dates, and for the periods presented, in conformity with U.S. GAAP.

Changes in Internal Control Over Financial Reporting

Except as described above, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

We may, from time to time, become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that may be, individually or in the aggregate, material to us.

ITEM 1A. RISK FACTORS.

In addition to the other information set forth in this report, you should carefully consider the factors discussed in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC on April 15, 2024, which could materially affect our business, financial condition or future results. The risks described in our Annual Report on Form 10-K, for the fiscal year ended December 31, 2023, as filed with the SEC on April 15, 2024, may not be the only risks facing the Company. Additional risks and uncertainties not currently known to the Company or that the Company currently deems to be immaterial also may materially adversely affect the Company's business, financial condition and/or operating results.

There were no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, as filed with the SEC on April 15, 2024.

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

There were no unregistered sales of equity securities during the period covered by this report.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

Rule 10b5-1 Trading Arrangements and Non-Rule 10b5-1 Trading Arrangements

During the fiscal quarter ended September 30, 2024, none of our officers or directors, as those terms are defined in Rule 16a-1(f), adopted or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as those terms are defined in Item 408 of Regulation S-K.

ITEM 6. EXHIBITS

Exhibit No.	Exhibit
1.1	Underwriting Agreement, dated August 20, 2024, between Reviva Pharmaceuticals Holdings, Inc. and Titan Partners Group LLC (incorporated by reference from Exhibit 1.1 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).
4.1	Form of Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).
4.2	Form of Pre-Funded Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).
4.3	Form of Underwriter Warrant from August 2024 Offering (incorporated by reference from Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).
4.4	Form of Warrant Amendment Agreement from August 2024 Offering (incorporated by reference from Exhibit 4.4 to the Company's Current Report on Form 8-K filed with the SEC on August 20, 2024).
31.1*	Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
31.2*	Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)
32.1**	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350
101.INS*	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
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 (formatted as Inline XBRL and contained in Exhibits 101)

* Filed herewith.

** The certifications furnished in Exhibit 32.1 hereto are deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and will not be deemed to be incorporated by reference into any filing under such Act or the Securities Act of 1933, as amended, except to the extent that the registrant specifically incorporates such certifications by reference.

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.

Reviva Pharmaceuticals Holdings, Inc.
(Registrant)

Date: November 14, 2024

/s/ Laxminarayan Bhat
Laxminarayan Bhat
Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2024

/s/ Narayan Prabhu
Narayan Prabhu
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Laxminarayan Bhat, hereby certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 14, 2024

/s/ Laxminarayan Bhat

Laxminarayan Bhat
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
Pursuant to
Securities Exchange Act Rules 13a-14(a) and 15d-14(a),
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Narayan Prabhu, hereby certify that:

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

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

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

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

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

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

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

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 14, 2024

/s/ Narayan Prabhu

Narayan Prabhu
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS OF CHIEF EXECUTIVE OFFICER
AND CHIEF FINANCIAL OFFICER
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 Reviva Pharmaceuticals Holdings, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly Report"), Laxminarayan Bhat, as Chief Executive Officer of the Company, and Narayan Prabhu, Chief Financial Officer of the Company, each hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350), to his knowledge:

1 The Quarterly Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
2 The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 14th day of November, 2024.

/s/ Laxminarayan Bhat	/s/ Narayan Prabhu
Laxminarayan Bhat	Narayan Prabhu
Chief Executive Officer	*Chief Financial Officer*
(Principal Executive Officer)	*(Principal Financial and Accounting Officer)*

This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002, or other document authenticating, acknowledging, or otherwise adopting the signatures that appear in typed form within the electronic version of this written statement required by Section 906, has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.