

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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended March 31, 2025

or

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

Commission file number: 001-38634

Reviva Pharmaceuticals Holdings, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

10080 N. Wolfe Road, Suite SW3-200
Cupertino, CA
(Address of principal executive offices)

85-4306526
(I.R.S. Employer Identification No.)

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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 May 12, 2025 the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 46,739,949.

REVIVA PHARMACEUTICALS HOLDINGS, INC.
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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements (Unaudited)
REVIVA PHARMACEUTICALS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	March 31, 2025	December 31, 2024
Assets		
Cash and cash equivalents	\$ 5,289,404	\$ 13,476,331
Prepaid clinical trial costs	211,855	540,601
Prepaid expenses and other current assets	756,066	666,435
Total current assets	6,257,325	14,683,367
Non-current prepaid clinical trial costs	819,721	819,721
Total Assets	\$ 7,077,046	\$ 15,503,088
Liabilities and Stockholders' Equity (Deficit)		
Liabilities		
Short-term debt	\$ 224,300	\$ 458,154
Accounts payable	4,721,043	6,283,430
Accrued clinical expenses	5,524,163	6,723,719
Accrued compensation	556,884	635,587
Other accrued liabilities	482,864	500,616
Total current liabilities	11,509,254	14,601,506
Warrant liabilities	27,816	89,010
Total Liabilities	11,537,070	14,690,516
Commitments and contingencies (Note 6)		
Stockholders' Equity (Deficit)		
Common stock, par value of \$0.0001; 315,000,000 shares authorized; 46,739,949 and 46,579,199 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	4,674	4,658
Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Additional paid-in capital	166,241,192	165,080,964
Accumulated deficit	(170,705,890)	(164,273,050)
Total stockholders' equity (deficit)	(4,460,024)	812,572
Total Liabilities and Stockholders' Equity (Deficit)	\$ 7,077,046	\$ 15,503,088

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended March 31,	
	2025	2024
Operating expenses		
Research and development	\$ 4,113,537	\$ 5,783,865
General and administrative	2,424,630	2,138,241
Total operating expenses	<u>6,538,167</u>	<u>7,922,106</u>
Loss from operations	<u>(6,538,167)</u>	<u>(7,922,106)</u>
Other income (expense)		
Gain on remeasurement of warrant liabilities	61,194	456,177
Interest expense	(11,620)	(3,487)
Interest income	86,111	173,098
Other (expense) income, net	(25,145)	(129,894)
Total other (expense) income, net	<u>110,540</u>	<u>495,894</u>
Loss before provision for income taxes	<u>(6,427,627)</u>	<u>(7,426,212)</u>
Provision for income taxes	5,213	7,396
Net loss	<u>\$ (6,432,840)</u>	<u>\$ (7,433,608)</u>
Net loss per share:		
Basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.25)</u>
Weighted average shares outstanding		
Basic and diluted	48,644,339	29,887,325

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)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Three Months Ended March 31, 2025					
Balance at December 31, 2024	46,579,199	\$ 4,658	\$ 165,080,964	\$ (164,273,050)	\$ 812,572
Common stock issued in connection with warrant exercises	160,750	16	241,109	—	241,125
Stock-based compensation expense	—	—	919,119	—	919,119
Net loss	—	—	—	(6,432,840)	(6,432,840)
Balance at March 31, 2025	<u>46,739,949</u>	<u>\$ 4,674</u>	<u>\$ 166,241,192</u>	<u>\$ (170,705,890)</u>	<u>\$ (4,460,024)</u>

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Three Months Ended March 31, 2024					
Balance at December 31, 2023	27,918,560	\$ 2,792	\$ 140,070,172	\$ (134,354,248)	\$ 5,718,716
Stock-based compensation expense	—	—	369,075	—	369,075
Net loss	—	—	—	(7,433,608)	(7,433,608)
Balance at March 31, 2024	<u>27,918,560</u>	<u>\$ 2,792</u>	<u>\$ 140,439,247</u>	<u>\$ (141,787,856)</u>	<u>\$ (1,345,817)</u>

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)

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (6,432,840)	\$ (7,433,608)
Adjustments to reconcile net loss to net cash used in operating activities		
Change in fair value of warrant liabilities	(61,194)	(456,177)
Stock-based compensation expense	919,119	369,075
Changes in operating assets and liabilities:		
Prepaid clinical trial costs (current and non-current)	328,746	(701,307)
Prepaid expenses and other current assets	(89,631)	(488,744)
Accounts payable	(1,562,387)	1,871,347
Accrued expenses and other current liabilities	(1,296,011)	(4,886,395)
Net cash used in operating activities	(8,194,198)	(11,725,809)
Cash flows from financing activities		
Proceeds from issuance of short-term debt	—	415,000
Repayment of short-term debt	(233,854)	(83,000)
Proceeds from exercise of warrants	241,125	—
Net cash provided by financing activities	7,271	332,000
Net decrease in cash and cash equivalents	(8,186,927)	(11,393,809)
Cash and cash equivalents, beginning of period	13,476,331	23,367,456
Cash and cash equivalents, end of period	\$ 5,289,404	\$ 11,973,647
Supplemental disclosures of cash flow information:		
Cash paid for taxes	\$ 1,075	\$ 657
Cash paid for interest	\$ 10,158	\$ 3,487

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

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 subsidiaries.

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 months ended March 31, 2025 are not necessarily indicative of the results that may be expected for the full year ending December 31, 2025.

The unaudited condensed consolidated balance sheet as of December 31, 2024, 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, 2024, which were included in our Annual Report on Form 10-K, as filed with the Securities and Exchange Commission ("SEC") on April 3, 2025.

Principles of consolidation

The accompanying condensed consolidated financial statements include the accounts of Reviva Pharmaceuticals Holdings, Inc. and its wholly owned subsidiaries Reviva Pharmaceuticals, Inc. and Reviva Pharmaceuticals India Pvt. Ltd. The Company's foreign 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) income, 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 subsidiaries have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation and used by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company and the Company's chief operating decision-maker ("CODM"), the Company's chief executive officer, view the Company's operations and manage its business as a single operating segment. See Note 8, "Segment Information," for more information.

Liquidity and going concern

The Company has incurred losses since inception and as of March 31, 2025 the Company had a working capital deficit of approximately \$5.3 million, an accumulated deficit of \$170.7 million and cash and cash equivalents on hand of approximately \$5.3 million. The Company's net loss for the three months ended March 31, 2025 and 2024, was approximately \$6.4 million and \$7.4 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 through the end of the second quarter of 2025, but will need additional fundraising activities and cash on hand during the third quarter of fiscal year 2025. 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. 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 consolidated 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 consolidated financial statements and the reported amounts of expenses during the reporting periods covered by the consolidated financial statements and accompanying notes. Significant items subject to such estimates and assumptions include clinical trial costs, fair value of stock-based compensation, and fair value of warrants. 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 \$1,093,816 and \$937,004 as of March 31, 2025 and December 31, 2024, 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 contracts with vendors and consultants to provide services related to the Company's research and development. Costs and expenses incurred that represented 10% or more of research and development costs for the three months ended March 31, 2025 and 2024 consisted of the following: during the three months ended March 31, 2025, costs from three vendors represented 53%, 18% and 12% of total research and development expenses, and during the three months ended March 31, 2024 costs from two vendors each represented 30% of total research and development expenses, respectively.

The Company's operating results may be materially affected by the foregoing factors.

Cash and cash equivalents

As of March 31, 2025, and December 31, 2024, 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 March 31, 2025	As of December 31, 2024
Cash on deposit	\$ 1,427,974	\$ 1,272,704
Money market funds (cash equivalents)	3,861,430	12,203,627
Cash and cash equivalents	<u>\$ 5,289,404</u>	<u>\$ 13,476,331</u>

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 equity classified warrants, the Company utilizes the Black-Scholes-Merton model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected dividend rate, and risk-free interest rates. In determining the fair value of liability classified warrants, the Company utilizes a Lattice model using assumptions regarding volatility of the Company's common share price, expected term of the warrants, expected dividend, and risk-free interest rates. These assumptions are described as:

- **Expected term:** The Company's expected term represents the period between the valuation date and the expiration date of the warrant; however, if an estimated liquidation event is expected to occur and the warrants are affected by said liquidation event, the period between the valuation date and that event would be used instead.
- **Expected volatility:** Expected volatility for equity classified awards is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the warrant. Expected volatility for liability classified warrants is based on the volatility implied by the public warrant market price when sufficient data is available; otherwise it is based on a peer set of similar public companies.
- **Expected dividend:** The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no plans to pay dividends.
- **Risk-free interest rate:** The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the valuation date for periods corresponding with the expected term of the warrant.

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.

Clinical trial costs

We record clinical trial costs as they are incurred. For any unbilled costs as of each reporting date, we determine the amounts to accrue by obtaining reports from the Company's contract research organization ("CRO") and communicating with our personnel and suppliers to identify services that have been performed, but not yet billed. We further validate the completeness of our accruals by reconciling payments and invoices, and reviewing vendor contracts and purchase orders. As necessary, we obtain milestones and percentage completion reports from vendors and will estimate the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of the actual cost.

Our estimated accrued expenses are based on facts and circumstances known to us at that time. We will confirm the accuracy of our estimates with the service providers and adjust if necessary. The significant estimates in our accrued clinical trial costs include the calculation of patient visits incurred, but not yet reported by the vendor. The calculation involves the use of key inputs and assumptions such as estimated budget, estimated unreported costs based on historical trending of reported costs to date, and projected costs remaining until the conclusion of the trials.

These estimates are primarily based on communications with the third-party service providers, the Company's estimates of accrued clinical trial costs and information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies from the estimate, the Company will adjust the accrual accordingly. The estimates are tuned up to reflect the best information available at the time of the consolidated financial statement issuance. Although the Company does not expect its estimates to be materially different from amounts actually incurred, the Company's estimate of the status and timing of services performed relative to the actual status and timing of services performed may vary.

Short-term debt

In December 2024, the Company obtained new financing for certain policy premiums related to Director and Officers liability insurance. 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 \$458,154. The financing arrangement has an annual percentage interest rate of 7.90% and a term of 10 months, with ten payments, inclusive of interest, payable on a monthly basis beginning January 2025 and continuing through October 2025.

New accounting pronouncements not yet adopted

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. This ASU was further clarified by ASU 2025-01, *Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses*, which was issued in December 2024. 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. NET 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 and pre-funded warrants outstanding during the period. Diluted net loss per share includes potentially dilutive securities such as stock options, and warrants to purchase common stock (excluding warrants that are exercisable for \$0.0001 per warrant) 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 months ended March 31, 2025 and 2024, 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 March 31,	
	2025	2024
Numerator:		
Net loss	\$ (6,432,840)	\$ (7,433,608)
Denominator:		
Weighted-average common shares outstanding – basic and diluted	48,644,339	29,887,325
Net loss per share – basic and diluted	<u>\$ (0.13)</u>	<u>\$ (0.25)</u>

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 March 31,	
	2025	2024
Shares issuable upon exercise of stock options	3,454,190	1,560,574
Shares issuable upon exercise of warrants to purchase common stock (excluding 1,968,765 warrants that are exercisable for \$0.0001 per warrant as of March 31, 2025 and 2024)	45,621,853	20,883,869
	<u>49,076,043</u>	<u>22,444,443</u>

The diluted net loss per share computation equals basic net loss per share for the three months ended March 31, 2025 and 2024, because the Company had a net loss and the impact of the assumed exercise of stock options and certain warrants would be anti-dilutive.

4. WARRANTS

The following is a summary of the Company's warrant activity (number of common stock shares underlying the warrants) for the three months ended March 31, 2025:

Warrant Issuance	Issuance	Exercise Price	Outstanding, December 31, 2024	Warrant Shares Granted	Warrant Shares Exercised	Warrant Shares Cancelled/Expired	Outstanding, March 31 2025	Expiration
SPAC Public Warrants	December 2020	\$ 11.50	6,881,313	—	—	—	6,881,313	December 2025
June 2021 Common Stock Warrants	June 2021	\$ 4.125	4,445,066	—	—	—	4,445,066	May 2026
June 2021 Common Stock Warrants (August 2024 Amended)*	June 2021	\$ 0.7964	2,199,975	—	—	—	2,199,975	August 2029
Pre-Public Private Company Warrants	December 2020	\$ 22.99	120,456	—	—	—	120,456	July 2025
September 2022 Private Pre-Funded Warrants	September 2022	\$ 0.0001	1,383,399	—	—	—	1,383,399	September 2027
September 2022 Common Stock Warrants	September 2022	\$ 2.40	1,383,399	—	—	—	1,383,399	September 2027
November 2023 Common Stock Warrants	November 2023	\$ 5.00	1,951,220	—	—	—	1,951,220	November, 2028
November 2023 Common Stock Warrants (May 2024 Amended)**	November 2023	\$ 1.455	1,365,854	—	—	—	1,365,854	May 2029
November 2023 Common Stock Warrants (August 2024 Amended)***	November 2023	\$ 0.7964	2,536,586	—	—	—	2,536,586	August 2029
November 2023 Pre-Funded Warrants	November 2023	\$ 0.0001	585,366	—	—	—	585,366	November, 2028
May 2024 Common Stock Warrants	May 2024	\$ 1.455	1,898,734	—	—	—	1,898,734	May 2029
August 2024 Common Stock Warrants	August 2024	\$ 0.7964	4,761,905	—	—	—	4,761,905	August 2029
August 2024 Underwriter Warrants	August 2024	\$ 1.3125	238,095	—	—	—	238,095	August 2029
December 2024 Series A Common Stock Warrants	December 2024	\$ 1.50	6,000,000	—	(55,250)	—	5,944,750	June 2025
December 2024 Series B Common Stock Warrants	December 2024	\$ 1.50	12,000,000	—	(105,500)	—	11,894,500	December 2029
			<u>47,751,368</u>	<u>—</u>	<u>(160,750)</u>	<u>—</u>	<u>47,590,618</u>	

* In August 2024, 2,199,975 of these warrants were modified to reduce the exercise price from \$4.125 per warrant share, to \$0.7964 per warrant share and to extend the expiration of these warrants from May 2026 to August 2029.

** In May 2024, 1,365,854 of these warrants were modified to reduce the exercise price from \$5.00 per warrant share, to \$1.455 per warrant share and to extend the expiration of these warrants from November 2028 to May 2029.

*** In August 2024, 2,536,586 of these warrants (separate from the May 2024 modification) were modified to reduce the exercise price from \$5.00 per warrant share, to \$0.7964 per warrant share and to extend the expiration of these warrants from November 2028 to August 2029.

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

Our authorized capital stock consists of:

- 315,000,000 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 March 31, 2025 there were 46,739,949 shares of our common stock outstanding, and no shares of preferred stock outstanding. As of December 31, 2024, there were 46,579,199 shares of our common stock outstanding, and no shares of preferred stock outstanding.

As of March 31, 2025, the Company has shares of common stock reserved for future issuance as follows:

Shares underlying outstanding warrants	47,590,618
Shares reserved for future grants under the 2020 Equity Incentive Plan	6,823,675
Shares underlying outstanding stock options	3,454,190
Total common stock reserved for future issuance	<u>57,868,483</u>

2020 Equity Incentive Plan

Subsequent to the December 31, 2024 balance sheet date, in accordance with the "evergreen" provision in our 2020 Equity Incentive Plan (the "Evergreen Provision"), an additional 4,657,919 shares were automatically made available for issuance on the first day of 2025, which represents 10% of the number of shares of common stock outstanding on December 31, 2024.

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 March 31, 2025 and 2024, the Company recorded stock-based compensation expense of approximately \$0.9 million and \$0.4 million, respectively. As of March 31, 2025, the Company had unrecognized stock-based compensation expense of \$2.7 million, which is expected to be recognized over a weighted-average period of 1.9 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 assumptions regarding volatility of the Company's common share price, expected term, expected dividend rate, and risk-free interest rates as described below:

- Expected term: The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding and is determined using the simplified method.
- Expected volatility: Expected volatility is based on historical stock volatility data for a peer set of similar public companies with sufficient trading history, over the expected term of the awards.
- Expected dividend: The Black-Scholes-Merton valuation model calls for a single expected dividend yield as an input. The Company has never paid dividends and has no plans to pay dividends.
- Risk-free interest rate: The risk-free interest rate used in the Black-Scholes-Merton valuation method is based on the U.S. Treasury zero-coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

The fair value of options granted during the three months ended March 31, 2025 used the following assumptions and key inputs:

Black-Scholes-Merton Inputs

	March 31, 2025
Risk-free interest rate	4.40%
Expected term (in years)	5.38
Expected volatility	110.00%
Expected dividend yield	—%

The weighted average fair value of stock options granted for the three months ended March 31, 2025 was \$1.48. The options have a contractual term of 10 years. No options were granted during the three months ended March 31, 2024.

Activity under the Company's equity compensation plan for the three months ended March 31, 2025 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, 2024	3,060,506	2,559,440	\$ 4.07	8.88	\$ 683,016
Granted	(894,750)	894,750	1.80		
Evergreen plan increase	4,657,919				
Balance, March 31, 2025	<u>6,823,675</u>	<u>3,454,190</u>	<u>\$ 3.48</u>	<u>8.95</u>	<u>\$ 1,219</u>
Options vested and exercisable at March 31, 2025		<u>2,143,223</u>	<u>\$ 3.98</u>	<u>8.72</u>	<u>\$ 1,219</u>

For the three months ended March 31, 2025 and 2024, the amount of stock-based compensation expense included within research and development and general and administrative expenses was as follows:

	Three Months Ended, March 31	
	2025	2024
Research and development	\$ 313,862	\$ 194,896
General and administrative	605,257	174,179
Total stock-based compensation expense	<u>\$ 919,119</u>	<u>\$ 369,075</u>

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 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.

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

The Company leases a corporate office located at 10080 N. Wolfe Road, Suite SW3-200, Cupertino, CA 95014. The lease was entered into beginning December 1, 2023 for a 12-month term with a monthly lease payment of approximately \$4,300. The lease was renewed in January 2025 for an additional twelve months, with a monthly lease payment of approximately \$4,600 applicable to the renewed lease. The operating lease cost on this lease (and renewal) for the three months ended March 31, 2025 and 2024 was approximately \$13,800 and \$11,200, 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 March 31, 2025 and December 31, 2024:

	March 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (cash equivalents)	\$ 3,861,430	\$ —	\$ —	\$ 3,861,430
Total assets measured and recorded at fair value	<u>\$ 3,861,430</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,861,430</u>
Liabilities:				
Warrant liabilities	\$ —	\$ —	\$ 27,816	\$ 27,816
Total liabilities measured and recorded at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 27,816</u>	<u>\$ 27,816</u>
	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (cash equivalents)	\$ 12,203,627	\$ —	\$ —	\$ 12,203,627
Total assets measured and recorded at fair value	<u>\$ 12,203,627</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 12,203,627</u>
Liabilities:				
Warrant liabilities	\$ —	\$ —	\$ 89,010	\$ 89,010
Total liabilities measured and recorded at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 89,010</u>	<u>\$ 89,010</u>

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 March 30,	
	2025	2024
Balance, beginning of period	\$ 89,010	\$ 806,655
Change in fair value of warrant liabilities	(61,194)	(456,177)
Balance, end of period	<u>\$ 27,816</u>	<u>\$ 350,478</u>

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 March 31, 2025 and December 31, 2024 as \$27,816 and \$89,010, respectively, using a Lattice model. The assumptions and key inputs used in the Lattice calculation were the following:

	March 31, 2025	December 31, 2024
Risk-free interest rate	4.15%	4.17%
Remaining expected term of Private Warrants	0.71	0.95
Expected volatility ⁽¹⁾	163.50%	128.70%
Stock price on valuation date	\$ 0.95	\$ 1.81
Exercise price	\$ 11.50	\$ 11.50
Expected dividend	—%	—%

(1) Based on volatility implied by the Company's publicly traded warrant market price.

8. SEGMENT INFORMATION

The Company views its operations and manages its business as one operating and reportable segment focused on developing new therapies that seek to address unmet medical needs in the areas of central nervous system ("CNS"), inflammatory and cardiometabolic diseases. The CODM manages and allocates resources to the operations of the Company on a consolidated basis, considering primarily research and development expenditures and net loss. This enables the Chief Executive Officer to assess the Company's overall level of available resources and determine how best to deploy these resources in line with long-term company-wide strategic goals.

Consistent with the Company's management reporting, results of operations are reported on a consolidated basis for purposes of segment reporting. Net loss is used to allocate resources and is reported on the condensed consolidated statements of operations. The measure of segment assets is reported on the condensed consolidated balance sheets as cash and cash equivalents.

The CODM does not review any measure of significant segment expenses or segment loss which differ from the level of reporting as reflected on the condensed consolidated statement of operations.

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, 2024 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," 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;
- 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 and Drug Administration 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;
- expectations regarding our ability to continue as a going concern;
- 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;
- 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;
- 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 ("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. On December 16, 2024, we announced positive preliminary topline data from the open label extension (the "OLE" or the "OLE Trial") portion of the RECOVER Trial evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia. See "Phase 3 RECOVER-1 Data" and "Open Label Extension (OLE) Trial Update" 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

Phase 3 RECOVER-1 Data

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:

Figure	Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
Figure 9	PANSS Total Score	10.1	0.6	< 0.001
Figure 10A	Positive Symptoms	2.8	0.5	< 0.001
Figure 10B	PANSS Excitement/Agitation	2.1	0.5	< 0.001
Figure 11A	Negative Symptoms (NS)	2	0.4	0.003
Figure 11B	NS Marder Factor	2.1	0.4	0.002
Figure 12A	PANSS Social Cognition	1.6	0.5	< 0.001
Figure 12B	Personal & Social Performance	6.3	0.5	< 0.001
Figure 13B	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 compared to placebo;
- 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, 1-year open label extension (OLE) trial evaluating long-term safety and tolerability (now complete, with full data set from the OLE trial expected in Q2-2025), and a soon to be initiated registrational global, randomized 4-week Phase 3 RECOVER 2 trial (the "RECOVER-2 Trial"). We reported positive preliminary topline data from the OLE in December 2024, with full data analysis of the OLE trial including long-term safety, tolerability and efficacy, as well as biomarker data, expected in Q2-2025. We expect to initiate the registrational RECOVER-2 Trial in mid-2025, subject to receipt of additional financing, with topline readout anticipated in the third quarter of 2026. RECOVER-2 was originally designed as a 6-week study, but after discussion between Reviva and FDA, the agency has agreed that it can be conducted as a 4-week study. Data from these brilaroxazine clinical trials will potentially support the planned NDA submission to the FDA in the fourth quarter of 2026.

Open Label Extension (OLE) Trial Update

The OLE portion of the RECOVER Study has been conducted globally at multiple centers to assess the safety, and efficacy of brilaroxazine at flexible doses of 15, 30 or 50 mg, administered once daily for 52-weeks (1-year) in patients with stable schizophrenia. The OLE included both rollover participants from the double-blind portion of RECOVER study and de novo participants with stable schizophrenia. Long-term safety data from a minimum of 100 patients who have completed 1-year of treatment is a requirement for brilaroxazine's NDA submission to the FDA.

As of May 2025, the long-term OLE portion of the RECOVER Phase 3 trial is complete, with the full data set from the OLE expected in Q2-2025.

- 446 patients have completed the trial
- 156 patients have completed 1-year (12 months) of treatment
- 301 patients have completed 6 months of treatment
- Biomarkers designed to independently support safety and 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

On December 16, 2024, we announced positive preliminary topline data from our OLE evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia. Administration of brilaroxazine once daily led to robust broad-spectrum efficacy that was sustained over 1 year. Brilaroxazine was generally well tolerated with no single side effect >5% and favorable compliance, with a discontinuation rate of 35% in the OLE part of this study. All three doses of brilaroxazine (15 mg, 30 mg and 50 mg) tested were efficacious and generally well-tolerated.

Key safety, efficacy and compliance findings for pooled analysis of brilaroxazine at 15, 30, and 50 mg include:

- As of December 2024, a total number of 435 patients were enrolled in the OLE across three dose groups: 139 in brilaroxazine 15 mg, 155 in brilaroxazine 30mg and 141 in brilaroxazine 50mg
- 156 (35.86%) rollover participants from the double-blind portion of the Phase 3 trial, while 279 (64.13%) de novo participants enrolled in the OLE
- Preliminary efficacy results are presented for 113 patients who completed 52 weeks (1 year) of treatment; preliminary safety results are presented for all 435 patients who enrolled in the OLE as of December 2024, including patients that are still participating in the trial

Brilaroxazine across doses improved major symptom domains of schizophrenia after 1-year of treatment:

- Dose dependent efficacy at the 15, 30, and 50 mg doses was observed, with decreases in PANSS total scores of -15.2, -18.6 and -20.8 points, respectively, from baseline to end-of-treatment at 52-week (1-year)
- Pooled data of brilaroxazine at the 15, 30, and 50 mg doses (N = 113) demonstrated clinically meaningful and sustained long-term (1-year) efficacy for schizophrenia with a significant decrease in PANSS total scores, PANSS positive symptoms, and PANSS negative symptoms compared to baseline
 - PANSS Total scores: 18.6-point decrease (71.6 □ 53), $p \leq 0.0001$
 - PANSS Positive Symptoms: 5.2-point decrease (17.7 □ 12.5), $p \leq 0.0001$
 - PANSS Negative Symptoms: 4.5-point decrease (19.5 □ 15.0), $p \leq 0.0001$
- Brilaroxazine demonstrated strong sustained efficacy from acute through maintenance treatment over 1-year with a decrease in PANSS Total score in rollover patients from the double-blind portion of the trial
 - ≥ 30 -point decrease of PANSS total in 86.76% of patients
 - ≥ 40 -point decrease of PANSS total in 64.70% of patients
 - ≥ 50 -point decrease of PANSS total in 33.82% of patients

Long-term clinical safety, tolerability and adherence findings of brilaroxazine administered for up to one year support a well-tolerated safety profile:

- 15.2% of participants reported at least one treatment-related adverse event (TRAE), which were mostly mild (12.2%) or moderate (3%) in severity and transient in nature
- Most common TRAEs $\geq 1\%$ were weight increase (3.2%), insomnia (1.8%) and somnolence (1.6%)
- Brilaroxazine was not associated with any clinically meaningful changes in movement disorder scales over 1-year treatment
- No drug-related serious adverse events (SAEs) observed or major safety concerns reported for brilaroxazine after up to 1-year of treatment; 3 serious adverse events were reported and none were related to brilaroxazine treatment
- Treatment discontinuation rate of 35% reported in this OLE, primarily due to withdrawal of consent (22%), participant lost to follow up (7%), and treatment-related adverse events (1.6%)

Collectively, the findings from the OLE (52-week/1-year) portion of the Phase 3 RECOVER study further strengthen the safety, efficacy and treatment adherence findings from the double-blind (4-week) portion of RECOVER.

Intellectual Property Overview

We are the sole owner of a patent portfolio that includes issued patents and pending patent applications covering compositions of matter and methods of use of our product candidates RP5063 (brilaroxazine) and RP1208, as well as related compounds. As of May 15, 2025 our portfolio of intellectual property consists of 70 granted patents and 12 pending patent applications in the United States and in over 20 foreign countries.

Brilaroxazine is our first intended commercial product. The original brilaroxazine patents include composition of matter, and methods of use in treating acute mania, autism, BD, depression, psychosis, and schizophrenia. One brilaroxazine original patent (U.S. Patent No. 8,188,076) and its 7 divisional/continuation patents have been granted in US. The original brilaroxazine patents have also been granted in the following foreign countries: Australia, Brazil, Canada, Germany, Spain, France, Great Britain, Hong Kong, Israel, India, Italy, Japan, S. Korea, Liechtenstein, Mexico, Russia, Slovakia, and Thailand; and pending in Columbia. We believe that our patent portfolio provides good protection of brilaroxazine. All of the US and foreign original brilaroxazine granted patents and pending patent applications will expire or are expected to expire in 2030, if a patent term extension is not obtained. If and when brilaroxazine receives regulatory approval, we intend to apply for patent term extensions on patents covering brilaroxazine in any jurisdiction where patent term extension is available. For example, the expiration date of the first US original brilaroxazine patent may be extendable up to 2035.

We also own additional brilaroxazine granted patents and pending patent applications for additional indications such as attention hyperactivity disorder (U.S. Patent No. 9,907,803, which will expire in 2035), pulmonary arterial hypertension (U.S. Patent No. 10,441,590, Japanese Patent No. 6787926, Chinese Patent No. CN107206007B, Hong Kong Patent No. 1244448, and European Patent No. 3244896; all of which will expire in 2036), and pulmonary fibrosis (U.S. Patent No. 12,053,477, Chinese Patent No. 111770755B, Japanese Patent No. 7343910, and pending applications in Brazil, Europe, and Hong Kong, which are expected to expire in 2038).

We also have two Patent Cooperation Treaty (PCT) applications pending, directed to a formulation of brilaroxazine and a method of using brilaroxazine for treating an indication.

We also have four U.S. provisional applications pending: one directed to using brilaroxazine for treating a specific symptom, and three directed to brilaroxazine compositions.

Financial Overview

We are a clinical-stage biopharmaceutical company and have not generated any revenues from the sale of products. We have never been profitable and have incurred losses since inception. As of March 31, 2025, we had a working capital deficit of approximately \$5.3 million, an accumulated deficit of \$170.7 million and cash and cash equivalents on hand of approximately \$5.3 million. Our net loss for the three months ended March 31, 2025 and 2024, was approximately \$6.4 million and \$7.4 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 product candidates. Furthermore, we continue to expect to incur additional costs associated with operating as a public company, which may increase now that we have exited emerging growth company status as of December 31, 2023, and as we continue our efforts to remediate the material weaknesses in our internal control over financial reporting that we identified as more particularly described in Item II, Part 9A of our fiscal year 2024 Annual Report on Form 10-K, and in this Quarterly Report on Form 10-Q below in Item 4. Controls and Procedures. We will need to generate significant revenues to achieve profitability, and we may never do so.

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

- invest significantly to further research and develop, through clinical trials for brilaroxazine, including completion of OLE activities, and our planned 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, and including in connection with our continuing efforts to remediate the material weaknesses in our internal control over financial reporting that we identified as more particularly described in Item II, Part 9A of our fiscal year 2024 Annual Report on Form 10-K, and in this Quarterly Report on Form 10-Q below in Item 4. Controls and Procedures

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 are as follows:

<u>Drug Candidate</u>	<u>Indication</u>	<u>Status</u>
Brilaroxazine (RP5063)	Schizophrenia	Conducted pivotal Phase 3 RECOVER-1 and long-term safety studies. Topline data for the RECOVER-1 Trial double-blind part announced October 30, 2023 -OLE positive preliminary topline data readout reported in December 2024, with full data set from the OLE expected in Q2-2025 -Phase 3 RECOVER-2 Trial expected initiation in mid-2025, subject to receipt of additional financing, with topline readout anticipated in the third quarter of 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 double-blind part in acute schizophrenia patients 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 OLE and our planned registrational RECOVER-2 Trial, we expect to incur substantial additional costs over the 2025-2026 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 \$67 million over the next approximately three years, consisting of our estimated costs for (i) completion of our OLE, (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 Trial and OLE 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, 2024, as filed with the SEC on April 3, 2025. Since the date of such Annual Report, there have been no material changes in our critical accounting estimates.

Results of Operations**Comparison of the three months ended March 31, 2025 and 2024:**

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended, March 31		Change	Change
	2025	2024	Amount	Percentage
Operating expenses				
Research and development	\$ 4,113,537	\$ 5,783,865	\$ (1,670,328)	(28.9)%
General and administrative	2,424,630	2,138,241	286,389	13.4%
Total operating expenses	<u>6,538,167</u>	<u>7,922,106</u>		
Loss from operations	<u>(6,538,167)</u>	<u>(7,922,106)</u>		
Gain on remeasurement of warrant liabilities	61,194	456,177	(394,983)	(86.6)%
Interest expense	(11,620)	(3,487)	(8,133)	233.2%
Interest income	86,111	173,098	(86,987)	(50.3)%
Other (expense) income, net	(25,145)	(129,894)	104,749	(80.6)%
Total other (expense) income, net	<u>110,540</u>	<u>495,894</u>		
Loss before provision for income taxes	<u>(6,427,627)</u>	<u>(7,426,212)</u>		
Provision for income taxes	5,213	7,396	(2,183)	(29.5)%
Net loss	<u>\$ (6,432,840)</u>	<u>\$ (7,433,608)</u>		

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 March 31, 2025 and 2024, research and development expenses were approximately \$4.1 million and \$5.8 million, respectively. Specifically, during the three months ended March 31, 2025 and 2024, our research and development costs consisted primarily of the following costs associated with our key research and development projects for advancing the clinical development of brilaroxazine during the reporting periods, which during such periods consisted primarily of our OLE Trial 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 \$0.8 million in each period (ii) internal stock-based compensation expenses with respect to employees involved in research and development activities, of approximately \$0.3 million and \$0.2 million, respectively; and (iii) external research and development expenses, of approximately \$3.0 million and \$4.8 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately \$2.1 million and \$3.3 million, respectively, non-clinical safety related costs of approximately \$0.6 million and \$0.3 million, respectively, non-clinical manufacturing related costs of approximately \$0.3 million and \$1.0 million, respectively, and non-clinical consulting and other related costs of an insignificant amount and \$0.2 million, respectively).

The decrease in research and development expenses for the three months ended March 31, 2025 as compared to the three months ended March 31, 2024 was primarily attributed to a decrease in external clinical research and development costs, partially attributed to a decrease in costs associated with patient visits as the OLE Trial winds down.

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 increased expenses associated with 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. Specifically, and without limiting the foregoing, we expect our expenses will increase as we begin our planned registrational RECOVER-2 Trial, which we expect to initiate in mid-2025, subject to receipt of additional financing. 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 Operation.

General and Administrative Expenses

For the three months ended March 31, 2025 and 2024, general and administrative expenses were approximately \$2.4 million and \$2.1 million, respectively. Specifically, during the three months ended March 31, 2025 and 2024, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately \$0.6 million and \$0.2 million, respectively; (ii) consultant and professional expenses of approximately \$0.9 million and \$1.0 million, respectively; (iii) legal expenses of approximately \$0.2 million in each period; (iv) employee related expenses of approximately \$0.6 million and \$0.5 million, respectively; (v) D&O insurance expenses of \$0.1 million approximately in each period; and (vi) other general and administrative expenses of an insignificant amount and approximately \$0.1 million, respectively.

Gain on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities gain of approximately \$0.1 million and \$0.5 million for the three months ended March 31, 2025 and 2024, respectively, resulting from the decrease in the calculated fair value of the warrants, principally as a result of the decrease in our stock price during both periods.

Interest Expense

We incurred interest expense of approximately \$12 thousand and \$3 thousand for the three months ended March 31, 2025 and 2024, respectively. The increase in interest expense is attributed to the interest rate on short term debt obtained by the Company related to Directors and Officers liability insurance policy premiums.

Interest Income

Interest income was approximately \$86 thousand and \$173 thousand for the three months ended March 31, 2025 and 2024, respectively. Interest income decreased by \$87 thousand primarily due to the lower cash and cash equivalents balance for the three months ended March 31, 2025 compared to the three months ended March 31, 2024.

Other (Expense) Income, net

Other (expense) income, net was approximately \$25 thousand for the three months ended March 31, 2025 and approximately \$130 thousand for the three months ended March 31, 2024. The decrease of approximately \$105 thousand was primarily attributable to a lower period-over-period foreign currency translation loss from favorable foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Liquidity and Capital Resources

	March 31, 2025	December 31, 2024	Change	
			Amount	Percentage
Balance Sheet Data:				
Cash and cash equivalents	\$ 5,289,404	\$ 13,476,331	\$ (8,186,927)	(60.8)%
Working (deficit) capital	(5,251,929)	81,861	(5,333,790)	(6515.7)%
Total assets	7,077,046	15,503,088	(8,426,042)	(54.4)%
Total stockholders' equity (deficit)	(4,460,024)	812,572	(5,272,596)	(648.9)%

	Three Months Ended March 31,		Change	
	2025	2024	Amount	Percentage
Statement of Cash Flow Data:				
Net cash used in operating activities	\$ (8,194,198)	\$ (11,725,809)	\$ 3,531,611	(30.1)%
Net cash provided by financing activities	7,271	332,000	(324,729)	(97.8)%
Net decrease in cash and cash equivalents	\$ (8,186,927)	\$ (11,393,809)	\$ 3,206,882	(28.1)%

Capital Resources

We have funded our operations to date primarily from the issuance and sale of our equity and convertible equity securities. As of March 31, 2025, we had cash and cash equivalents of approximately \$5.3 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 through the end of the second quarter of 2025, but will need additional fundraising activities and cash on hand during the third quarter of fiscal year 2025. 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 consolidated 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, 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.

During the three months ended March 31, 2025, there were 160,750 common stock warrants exercised at an exercise price of \$1.50 per warrant share.

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 three months ended March 31, 2025 was approximately \$8.2 million, consisting primarily of a net loss of approximately \$6.4 million, adjusted for non-cash items, including a change in fair value of warrant liabilities gain of approximately \$0.1 million, and stock-based compensation expense of approximately \$0.9 million, coupled with a decrease in our operating assets and liabilities totaling approximately \$2.6 million. The \$2.6 million decrease in net operating assets and liabilities was primarily due to a decrease in accrued clinical expenses and other accrued expenses and accounts payable coupled with an increase in prepaid expenses and other current assets, net with a decrease in prepaid clinical trial costs.

Net cash used in operating activities for the three months ended March 31, 2024, was approximately \$11.7 million, consisting primarily of a net loss of approximately \$7.4 million, adjusted for non-cash items, including a change in fair value of warrant liabilities gain of approximately \$0.5 million, and partially offset by stock-based compensation expense of approximately \$0.4 million, coupled with a decrease in our operating assets and liabilities totaling approximately \$4.2 million. The \$4.2 million decrease in net operating assets and liabilities was primarily due 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 an increase in accrued compensation.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the three months ended March 31, 2025 was approximately \$7.3 thousand. Cash provided by financing activities was attributable to approximately \$241.1 thousand in proceeds from the exercise of common stock warrants, which is offset by repayments on the short-term debt of approximately \$233.9 thousand.

Net cash provided by financing activities for the three months ended March 31, 2024 was approximately \$332.0 thousand. Cash provided by financing activities was attributable to approximately \$415.0 thousand in proceeds from the issuance of short-term debt and offset by the repayments of short-term debt of approximately \$83.0 thousand.

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 implementation 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 March 31, 2025. Based on such evaluation, as a result of the material weaknesses in internal control over financial reporting described below, our principal executive officer and principal financial officer have concluded that, as of March 31, 2025, our disclosure controls and procedures were not effective at the reasonable assurance level.

We identified the following entity-level material weaknesses. We have an ineffective control environment, including an insufficient number of personnel with an appropriate level of knowledge and experience to create the proper environment for effective internal control over financial reporting, and did not maintain the other components of the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), including appropriate risk assessment, control activities, information and communication, and monitoring activities components relating to (i) sufficiency of processes related to identifying and analyzing risks to the achievement of objectives, including technology, across the entity, (ii) developing general control activities over technology to support the achievement of objectives across the entity, (iii) sufficiency of selecting and developing control activities that contribute to the mitigation of risks to the achievement of objectives to acceptable levels and (iv) sufficiency of monitoring activities to ascertain whether the components of internal control are present and functioning.

The entity-level material weaknesses contributed to other material weaknesses within our system of internal control over financial reporting as follows:

- We did not design and maintain effective information technology (IT) general controls for certain information systems supporting our key financial reporting processes. Specifically, we did not design and maintain (a) change management controls to ensure that program and data changes affecting financial applications and underlying accounting records are identified, tested, authorized and implemented appropriately, (b) access controls to ensure appropriate IT segregation of duties are maintained that adequately restrict and segregate privileged access between environments which support development and production, (c) controls to monitor on an on-going basis for the proper segregation of privileged access between environments which support development and production and (d) operations controls to ensure appropriate interfacing between systems. As a result, IT application controls and business process controls (automated and manual) that are dependent on the ineffective IT general controls, or that rely on data produced from systems impacted by the ineffective IT general controls, are also deemed ineffective.
- We did not design and maintain effective process-level controls, which affects substantially all account balances and disclosures.

These material weaknesses have a pervasive impact and consequently, impact control activities over all financial statement account balances, classes of transactions, and disclosures.

Management's Remediation Measures

We are committed to continuing to improve our internal control over financial reporting, and also our IT general controls. As of the date hereof, we have commenced procedures to remediate the material weaknesses, including engaging a third-party consulting firm to assist with the enhancement of IT general controls over information systems relevant to financial reporting, including privileged access and segregation of duties; and with continued realignment of existing personnel to strengthen management's review and documentation over internal control over financial reporting.

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 unaudited condensed consolidated financial statements 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 GAAP.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 the 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

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.

Our business is subject to substantial risks and uncertainties. An investment in our securities involves a high degree of risk. The information presented below supplements the risk factors previously disclosed in "Part I, Item 1A. Risk Factors," in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the SEC on April 3, 2025. In addition to the other information set forth in this report and in our other SEC filings from time to time, 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, 2024, as filed with the SEC on April 3, 2025, as supplemented by the information below, 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, 2024, as filed with the SEC on April 3, 2025, as supplemented by the information below, 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. Except as required by the federal securities law, we undertake no obligation to update or revise any risk factor, whether as a result of new information, future events or otherwise.

If we fail to regain compliance with the continued listing requirements of Nasdaq, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed for trading on Nasdaq. On May 13, 2025, we received notice from Nasdaq indicating that we are not in compliance with the requirement to maintain a minimum bid price of \$1.00 per share for continued listing on Nasdaq (the "minimum closing bid price requirement"). We were provided an initial compliance period of 180 calendar days from the date of the notice, or until November 10, 2025, to regain compliance with the minimum closing bid price requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). We may be eligible for an additional 180 calendar day compliance period. There can be no assurance that we will regain compliance with the minimum closing bid price requirement during the 180-day compliance period, secure a second period of 180 days to regain compliance or maintain compliance with the other Nasdaq listing requirements.

We will continue to monitor the closing bid price of our common stock and assess potential actions to regain compliance with the minimum closing bid price requirement and may, if appropriate, consider and effectuate available options, including implementation of a reverse stock split of our common stock. If we implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock.

We must regain compliance with Nasdaq's minimum closing bid price requirement of \$1.00 per share (and must continue to maintain compliance with Nasdaq's other continued listing requirements), or risk delisting, which could have a material adverse effect on our business. If our common stock is delisted from Nasdaq, it could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, suppliers, contractual counterparties, and employees and fewer business development opportunities.

If our common stock were delisted, it could be more difficult to buy or sell our common stock or to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair our ability to raise capital on acceptable terms, if at all.

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.

Notice of Failure to Satisfy a Continued Listing Rule or Standard – Nasdaq Minimum Bid Price Rule

On May 13, 2025, we received written notice (the "Notice") from The Nasdaq Stock Market LLC ("Nasdaq") that the closing bid price for our common stock had been below \$1.00 per share for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued listing on the Nasdaq Capital Market as set forth in Nasdaq Listing Rule 5550(a)(2).

The Notice has no immediate effect on the listing or trading of our common stock on the Nasdaq Capital Market.

In accordance with the Nasdaq Listing Rule 5810(c)(3)(A), we have a period of 180 calendar days, or until November 10, 2025, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of ten consecutive business days during this 180-day period.

If we are not in compliance by November 10, 2025, we may qualify for a second 180 calendar-day period to regain compliance. If we do not qualify for, or fail to regain compliance during the second compliance period, then Nasdaq will notify us of Nasdaq's determination to delist our common stock, at which point we would have an option to appeal the delisting determination to a Nasdaq hearings panel.

We intend to actively monitor the closing bid price of our common stock and may, if appropriate, consider implementing available strategies to regain compliance with the minimum bid price requirement under the Nasdaq Listing Rules.

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

During the fiscal quarter ended March 31, 2025, 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
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 Exhibit 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: May 15, 2025

By: /s/ Laxminarayan Bhat

Laxminarayan Bhat
Chief Executive Officer
(Principal Executive Officer)

Date: May 15, 2025

By: /s/ Narayan Prabhu

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

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: May 15, 2025

/s/ Laxminarayan Bhat

Laxminarayan Bhat

Chief Executive Officer

(Principal Executive Officer)

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; 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: May 15, 2025

/s/ Narayan Prabhu

Narayan Prabhu

Chief Financial Officer

(Principal Financial and Accounting Officer)

**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 March 31, 2025, 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, as 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 15th day of May, 2025.

/s/ Laxminarayan Bhat

Laxminarayan Bhat

Chief Executive Officer

(Principal Executive Officer)

/s/ Narayan Prabhu

Narayan Prabhu

Chief Financial 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.