

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 September 30, 2025

or

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

Commission file 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)

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

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

95014
(Zip Code)

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

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

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

<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 ☒ 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 ☒ 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 ☒

Smaller reporting company ☒

Emerging growth company ☐

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

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

As of November 11, 2025 the number of outstanding shares of the registrant's common stock, par value \$0.0001 per share, was 115,058,619.

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

	Page
Part I Financial Information	
Item 1. Financial Statements (unaudited)	F-1
Condensed Consolidated Balance Sheets as of September 30, 2025 and December 31, 2024	F-1
Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2025 and 2024	F-2
Condensed Consolidated Statements of Stockholders' Equity (Deficit) for the three and nine months ended September 30, 2025 and 2024	F-3
Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2025 and 2024	F-5
Notes to Condensed Consolidated Financial Statements	F-6
Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations	1
Item 3. Quantitative and Qualitative Disclosures About Market Risk	17
Item 4. Controls and Procedures	17
Part II Other Information	19
Item 1. Legal Proceedings	19
Item 1A. Risk Factors	19
Item 2. Unregistered Sales of Equity Securities and Use of Proceeds	20
Item 3. Defaults Upon Senior Securities	20
Item 4. Mine Safety Disclosures	20
Item 5. Other Information	20
Item 6. Exhibits	21
Signatures	22

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	\$ 13,183,259	\$ 13,476,331
Prepaid clinical trial costs	81,742	540,601
Prepaid expenses and other current assets	247,927	666,435
Total current assets	13,512,928	14,683,367
Non-current prepaid clinical trial costs	819,721	819,721
Total Assets	\$ 14,332,649	\$ 15,503,088
Liabilities and Stockholders' Equity		
Liabilities		
Short-term debt	\$ —	\$ 458,154
Accounts payable	5,431,806	6,283,430
Accrued clinical expenses	2,891,175	6,723,719
Accrued compensation	784,956	635,587
Other accrued liabilities	630,471	500,616
Total current liabilities	9,738,408	14,601,506
Warrant liabilities	44,506	89,010
Total Liabilities	9,782,914	14,690,516
Commitments and contingencies (Note 6)		
Stockholders' Equity		
Common stock, par value of \$0.0001; 315,000,000 shares authorized; 96,337,119 and 46,579,199 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	9,618	4,658
Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024	—	—
Additional paid-in capital	185,310,390	165,080,964
Accumulated deficit	(180,770,273)	(164,273,050)
Total stockholders' equity	4,549,735	812,572
Total Liabilities and Stockholders' Equity	\$ 14,332,649	\$ 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 2,131,444	\$ 6,858,285	\$ 9,969,736	\$ 18,226,497
General and administrative	1,898,397	1,604,249	6,671,254	6,287,786
Total operating expenses	4,029,841	8,462,534	16,640,990	24,514,283
Loss from operations	(4,029,841)	(8,462,534)	(16,640,990)	(24,514,283)
Other income (expense)				
(Loss) gain on remeasurement of warrant liabilities	(27,816)	72,321	44,504	728,771
Interest expense	(2,605)	(5,146)	(19,022)	(13,786)
Interest income	59,103	53,248	168,061	313,956
Other expense, net	(6,774)	(23,687)	(33,769)	(159,202)
Total other income, net	21,908	96,736	159,774	869,739
Loss before provision for income taxes	(4,007,933)	(8,365,798)	(16,481,216)	(23,644,544)
Provision for income taxes	2,840	—	16,007	14,781
Net loss	\$ (4,010,773)	\$ (8,365,798)	\$ (16,497,223)	\$ (23,659,325)
Net loss per share:				
Basic and diluted	\$ (0.06)	\$ (0.25)	\$ (0.29)	\$ (0.75)
Weighted average shares outstanding				
Basic and diluted	72,685,740	33,804,693	57,147,381	31,424,395

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	Accumulated	Total Stockholders' Equity (Deficit)
Three Months Ended September 30, 2025	Shares	Amount	Capital	Deficit	
Balance at June 30, 2025	68,003,613	\$ 6,800	\$176,293,553	\$(176,759,500)	\$ (459,147)
Issuance of common stock in At-The-Market (ATM) offering, net of transaction costs	1,183,506	118	500,855	—	500,973
Issuance of common stock in September 2025 public offering, net of transaction costs	27,000,000	2,700	3,362,148	—	3,364,848
Issuance of common stock warrants in September 2025 public offering, net of transaction costs	—	—	4,695,455	—	4,695,455
Vesting of restricted common stock issued to consultant in exchange for services	150,000	—	—	—	—
Stock-based compensation expense	—	—	458,379	—	458,379
Net loss	—	—	—	(4,010,773)	(4,010,773)
Balance at September 30, 2025	<u>96,337,119</u>	<u>\$ 9,618</u>	<u>\$185,310,390</u>	<u>\$(180,770,273)</u>	<u>\$ 4,549,735</u>

	Common Stock		Additional Paid-In	Accumulated	Total Stockholders' Equity (Deficit)
Nine Months Ended September 30, 2025	Shares	Amount	Capital	Deficit	
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
Issuance of common stock in At-The-Market (ATM) offering, net of transaction costs	2,447,170	244	1,191,331	—	1,191,575
Issuance of common stock in June 2025 and September 2025 public offerings, net of transaction costs	47,000,000	4,700	7,258,095	—	7,262,795
Issuance of common stock warrants in June 2025 and September 2025 public offerings, net of transaction costs	—	—	9,766,116	—	9,766,116
Vesting of restricted common stock issued to consultant in exchange for services	150,000	—	—	—	—
Stock-based compensation expense	—	—	1,772,775	—	1,772,775
Net loss	—	—	—	(16,497,223)	(16,497,223)
Balance at September 30, 2025	<u>96,337,119</u>	<u>\$ 9,618</u>	<u>\$185,310,390</u>	<u>\$(180,770,273)</u>	<u>\$ 4,549,735</u>

REVIVA PHARMACEUTICALS HOLDINGS, INC.

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

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

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

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

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities		
Net loss	\$ (16,497,223)	\$ (23,659,325)
Adjustments to reconcile net loss to net cash used in operating activities		
Change in fair value of warrant liabilities	(44,504)	(728,771)
Stock-based compensation expense	1,772,775	1,076,125
Changes in operating assets and liabilities:		
Prepaid clinical trial costs (current and non-current)	458,859	(1,666,952)
Prepaid expenses and other current assets	418,508	(71,171)
Accounts payable	(1,210,527)	4,928,471
Accrued expenses and other current liabilities	(3,694,320)	(4,321,796)
Net cash used in operating activities	(18,796,432)	(24,443,419)
Cash flows from financing activities		
Proceeds from issuance of short-term debt	—	415,000
Repayment of short-term debt	(458,154)	(332,000)
Proceeds from issuance of common stock in ATM offering, net of transaction costs paid	1,300,686	—
Proceeds from issuance of common stock, common stock warrants, prefunded warrants and from modification of existing warrants, in offerings, net of transaction costs paid	17,419,703	6,551,745
Proceeds from exercise of common stock warrants	241,125	35
Net cash provided by financing activities	18,503,360	6,634,780
Net decrease in cash and cash equivalents	(293,072)	(17,808,639)
Cash and cash equivalents, beginning of period	13,476,331	23,367,456
Cash and cash equivalents, end of period	\$ 13,183,259	\$ 5,558,817
Supplemental disclosures of cash flow information:		
Cash paid for taxes	\$ 3,369	\$ 3,417
Cash paid for interest	\$ 19,022	\$ 13,786
Noncash Investing and Financing Activities:		
Settlement of bonuses in form of stock options	\$ —	\$ 330,816
Warrant modification recorded in stockholders' equity (deficit)	\$ —	\$ 1,073,416
Issuance of common stock warrants	\$ 9,766,116	\$ 2,310,699
Issuance of underwriter warrants	\$ —	\$ 165,952
Transaction costs related to offerings included in accounts payable and accrued expenses	\$ 499,903	\$ —

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

Reviva Pharmaceuticals Holdings, Inc. (together with its consolidated subsidiaries, 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.

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.

On December 14, 2020, the Company completed a business combination pursuant to which Tenzing Merger Subsidiary Inc., a wholly-owned subsidiary of Tenzing Acquisition Corp., merged with and into Reviva Pharmaceuticals, Inc., with Reviva Pharmaceuticals, Inc. surviving the merger. As a result, Reviva Pharmaceuticals, Inc. became a wholly-owned subsidiary of the Company. 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.

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 the Company’s annual consolidated financial statements and notes thereto and include all adjustments, consisting of normal recurring items, considered necessary for the fair presentation of the consolidated financial position and results of operations of the Company for all interim periods presented. The operating results for the three and nine months ended September 30, 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 the Company’s consolidated financial statements and notes thereto for the year ended December 31, 2024, which were included in the Company’s 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 transaction gain or loss each reporting period as part of other expense, net, on the condensed consolidated statement of operations. The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. GAAP. All transactions and balances between the parent and its 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 ("CODM") in deciding how to allocate resources and assess performance. The Company and the Company's 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 September 30, 2025, the Company had a working capital surplus of approximately \$3.8 million, an accumulated deficit of \$180.8 million and cash and cash equivalents on hand of approximately \$13.2 million. The Company's net loss for the three months ended September 30, 2025 and 2024, was approximately \$4.0 million and \$8.4 million, respectively. The Company's net loss for the nine months ended September 30, 2025 and 2024, was approximately \$16.5 million and \$23.7 million, respectively. The Company expects to incur significant expenses and increased operating losses for the next several years. The Company expects its expenses to increase in connection with its ongoing activities to research, develop and commercialize its product candidates. The Company will need to generate significant revenues to achieve profitability, and it may never do so.

The Company's current cash on hand is not sufficient to satisfy its operating cash needs for the 12 months from the filing of this Quarterly Report on Form 10-Q. The Company believes that it has adequate cash on hand to cover anticipated outlays into the second quarter of 2026 but will need additional fundraising activities and cash on hand during the 2026 fiscal year. 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 the Company's future funding requirements will depend on many factors, including the pace and results of the Company's 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, discontinuing certain clinical activities or ceasing operations. 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 condensed consolidated financial statements and the reported amounts of expenses during the reporting periods covered by the condensed 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 \$933,723 and \$937,004 as of September 30, 2025 and December 31, 2024, respectively. To date, 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 and nine months ended September 30, 2025 and 2024 consisted of the following: during the three months ended September 30, 2025, costs from two vendors each represented 28% and 10% of total research and development expenses, respectively; during the three months ended September 30, 2024 costs from two vendors each represented 64% and 10% of total research and development expenses, respectively; during the nine months ended September 30, 2025 costs from one vendor represented 39% of total research and development expenses; and during the nine months ended September 30, 2024 costs from two vendors each represented 37% and 17% 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 September 30, 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 September 30, 2025	As of December 31, 2024
Cash on deposit	\$ 1,265,414	\$ 1,272,704
Money market funds (cash equivalents)	11,917,845	12,203,627
Cash and cash equivalents	<u>\$ 13,183,259</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, or Company stock volatility when sufficient trading history exists. 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

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

The Company's estimated accrued expenses are based on facts and circumstances known to it at that time. The Company will confirm the accuracy of its estimates with the service providers and adjust if necessary. The significant estimates in the Company's 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 trued 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 provided for 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. The Company paid the remaining balance of the short-term debt during the three months ended September 30, 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 and nine months ended September 30, 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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Numerator:				
Net loss	\$ (4,010,773)	\$ (8,365,798)	\$(16,497,223)	\$(23,659,325)
Denominator:				
Weighted-average common shares outstanding – basic and diluted	72,685,740	33,804,693	57,147,381	31,424,395
Net loss per share – basic and diluted	<u>\$ (0.06)</u>	<u>\$ (0.25)</u>	<u>\$ (0.29)</u>	<u>\$ (0.75)</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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Shares issuable upon exercise of stock options	3,129,190	1,813,387	3,129,190	1,813,387
Shares of unvested restricted common stock issuable to consultant in the future in exchange for services to be provided	150,000	—	150,000	—
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 September 30, 2025 and 2024)	133,556,647	27,782,603	133,556,647	27,782,603
	<u>136,835,837</u>	<u>29,595,990</u>	<u>136,835,837</u>	<u>29,595,990</u>

The diluted net loss per share computation equals basic net loss per share for the three and nine months ended September 30, 2025 and 2024 because the Company had a net loss and the impact of the assumed exercise of stock options, future vesting of restricted stock 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 nine months ended September 30, 2025:

Warrant Issuance	Issuance Date	Exercise Price	Outstanding, December 31, 2024	Warrant Shares Issued	Warrant Shares Exercised	Warrant Shares Cancelled / Expired	Outstanding, September 30 2025	Expiration Date
SPAC Public Warrants June 2021 Common Stock Warrants	December 2020	\$ 11.50	6,881,313	—	—	—	6,881,313	December 2025
Common Stock Warrants (August 2024 Amended)*	June 2021	\$ 4.125	4,445,066	—	—	—	4,445,066	May 2026
Pre-Public Private Company Warrants September 2022	June 2021	\$ 0.7964	2,199,975	—	—	—	2,199,975	August 2029
Private Pre-Funded Warrants September 2022	December 2020	\$ 22.99	120,456	—	—	(120,456)	—	July 2025
Common Stock Warrants November 2023	September 2022	\$ 0.0001	1,383,399	—	—	—	1,383,399	September 2027
Common Stock Warrants (May 2024 Amended)**	September 2022	\$ 2.40	1,383,399	—	—	—	1,383,399	September 2027
Common Stock Warrants (August 2024 Amended)***	November 2023	\$ 5.00	1,951,220	—	—	—	1,951,220	November, 2028
Common Stock Warrants (August 2024 Amended)***	November 2023	\$ 1.455	1,365,854	—	—	—	1,365,854	May 2029
Pre-Funded Warrants May 2024	November 2023	\$ 0.7964	2,536,586	—	—	—	2,536,586	August 2029
Common Stock Warrants August 2024	November 2023	\$ 0.0001	585,366	—	—	—	585,366	November 2028
Common Stock Warrants August 2024	May 2024	\$ 1.455	1,898,734	—	—	—	1,898,734	May 2029
Underwriter Warrants December 2024	August 2024	\$ 0.7964	4,761,905	—	—	—	4,761,905	August 2029
Series A Common Stock Warrants December 2024	August 2024	\$ 1.3125	238,095	—	—	—	238,095	August 2029
Series B Common Stock Warrants June 2025	December 2024	\$ 1.50	6,000,000	—	(55,250)	(5,944,750)	—	June 2025
Series C Common Stock Warrants June 2025	December 2024	\$ 1.50	12,000,000	—	(105,500)	—	11,894,500	December 2029
Series D Common Stock Warrants September 2025	June 2025	\$ 0.50	—	20,000,000	—	—	20,000,000	June 2030
Series E Common Stock Warrants September 2025	June 2025	\$ 0.50	—	20,000,000	—	—	20,000,000	June 2026
Series F Common Stock Warrants September 2025	September 2025	\$ 0.335	—	27,000,000	—	—	27,000,000	September 2030
	September 2025	\$ 0.335	—	27,000,000	—	—	27,000,000	September 2026
			<u>47,751,368</u>	<u>94,000,000</u>	<u>(160,750)</u>	<u>(6,065,206)</u>	<u>135,525,412</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.

June 2025 Public Offering

On June 26, 2025, the Company entered into a placement agency agreement (the “June 2025 Placement Agency Agreement”) with A.G.P./Alliance Global Partners, as the placement agent (the “Placement Agent”), pursuant to which the Company sold in a public offering (i) an aggregate of 20,000,000 shares of the Company’s common stock, (ii) Series C warrants exercisable for an aggregate of up to 20,000,000 shares of common stock (the “Series C Common Warrants”) and (iii) Series D warrants exercisable for an aggregate of up to 20,000,000 shares of common stock (the “Series D Common Warrants” and together with the Series C Common Warrants, the “June 2025 Warrants”), for aggregate gross proceeds of \$10.0 million (the “June 2025 Public Offering”). Each share of common stock was sold together with (i) a Series C Common Warrant to purchase one share of common stock and (ii) a Series D Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.50 per share of common stock and accompanying June 2025 Warrants. The Series C Common Warrants are exercisable immediately upon issuance, have a term of five years from the date of issuance and have an exercise price of \$0.50 per share. The Series D Common Warrants are exercisable immediately upon issuance, have a term of twelve months from the date of issuance and have an exercise price of \$0.50 per share. The net proceeds to the Company from the June 2025 Public Offering were approximately \$9.0 million, after deducting placement agent fees and expenses and other offering expenses payable by the Company.

The Company evaluated the June 2025 Warrants in accordance with the guidance at ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The June 2025 Warrants are indexed to the Company’s common stock and are required to be settled through physical settlement or net share settlement, if exercised. Accordingly, the June 2025 Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The fair value of the June 2025 Warrants was determined utilizing a Black-Scholes model considering all relevant assumptions current at the date of issuance. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for further detail regarding how these assumptions were determined. The grant date relative fair value of the Series C and Series D Common Warrants was estimated to be \$3.1 million and \$2.0 million, respectively recognized as additional paid-in capital in the condensed consolidated balance sheet as they were determined to be equity classified and categorized as Level 3 within the fair value hierarchy.

The following assumptions and key inputs were used to value the June 2025 Warrants at the date of issuance:

	Series C Common Stock Warrants	Series D Common Stock Warrants
Risk-free interest rate	3.8%	4.0%
Expected term (years)	5.00	1.00
Expected volatility	119.00%	157.00%
Stock price on valuation date	\$ 0.36	\$ 0.36
Exercise price	\$ 0.50	\$ 0.50
Expected dividend	—%	—%

September 2025 Public Offering

On September 18, 2025, the Company entered into a placement agency agreement (the “September 2025 Placement Agency Agreement”) with the Placement Agent, pursuant to which the Company sold in a public offering (i) an aggregate of 27,000,000 shares of the Company’s common stock, (ii) Series E warrants exercisable for an aggregate of up to 27,000,000 shares of common stock (the “Series E Common Warrants”) and (iii) Series F warrants exercisable for an aggregate of up to 27,000,000 shares of common stock (the “Series F Common Warrants” and together with the Series E Common Warrants, the “September 2025 Warrants”), for aggregate gross proceeds of \$9.0 million (the “September 2025 Public Offering”). Each share of common stock was sold together with (i) a Series E Common Warrant to purchase one share of common stock and (ii) a Series F Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.335 per share of common stock and accompanying September 2025 Warrants. The Series F Common Warrants are exercisable immediately upon issuance, have a term of five years from the date of issuance and have an exercise price of \$0.335 per share. The Series E Common Warrants are exercisable immediately upon issuance, have a term of twelve months from the date of issuance and have an exercise price of \$0.335 per share. The net proceeds to the Company from the September 2025 Public Offering were approximately \$8.1 million, after deducting placement agent fees and expenses and other offering expenses payable by the Company.

The Company evaluated the September 2025 Warrants in accordance with the guidance at ASC 480, *Distinguishing Liabilities from Equity* and ASC 815-40, *Derivatives and Hedging*, and determined that they should be classified as equity instruments, with no recurring fair value measurement required. The September 2025 Warrants are indexed to the Company's common stock and are required to be settled through physical settlement or net share settlement, if exercised. Accordingly, the September 2025 Warrants were recorded at their grant date fair value with no subsequent remeasurement.

The fair value of the September 2025 Warrants was determined utilizing a Black-Scholes model considering all relevant assumptions current at the date of issuance. Refer to Note 2, *Summary of Significant Accounting Policies and Basis of Presentation*, for further detail regarding how these assumptions were determined. The grant date relative fair value of the Series E Common Warrants and Series F Common Warrants was estimated to be \$2.9 million and \$1.8 million, respectively, recognized as additional paid-in capital in the condensed consolidated balance sheet as they were determined to be equity classified and categorized as Level 3 within the fair value hierarchy.

The following assumptions and key inputs were used to value the September 2025 Warrants at the date of issuance:

	Series E Common Stock Warrants	Series F Common Stock Warrants
Risk-free interest rate	3.7%	3.6%
Expected term (years)	5.00	1.00
Expected volatility	129.00%	154.00%
Stock price on valuation date	\$ 0.31	\$ 0.31
Exercise price	\$ 0.335	\$ 0.335
Expected dividend	—%	—%

5. STOCKHOLDERS' EQUITY (DEFICIT), 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 September 30, 2025 there were 96,337,119 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 September 30, 2025, the Company has shares of common stock reserved for future issuance as follows:

Shares underlying outstanding warrants	135,525,412
Shares reserved for future grants under the 2020 Equity Incentive Plan	6,848,675
Shares underlying outstanding stock options	3,129,190
Total common stock reserved for future issuance	<u>145,503,277</u>

May 2025 ATM Sales Agreement

On May 30, 2025, the Company entered into an at market issuance sales agreement (the “May 2025 ATM Sales Agreement”) with B. Riley Securities, Inc. and Alliance Global Partners serving as agents (the “Agents”), with respect to an at-the-market (“ATM”) offering program under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering price of up to \$50 million through the Agents. During the three months ended September 30, 2025, the Company sold 1,183,506 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of approximately \$0.5 million after deducting sales agent commissions and other offering expenses of approximately \$30.8 thousand. During the nine months ended September 30, 2025, the Company sold 2,447,170 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of approximately \$1.2 million after deducting sales agent commissions and other offering expenses of approximately \$0.4 million.

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 (the “Evergreen Shares”) were automatically made available for issuance for future awards under such plan on the first day of 2025, which represents 10% of the number of shares of common stock outstanding on December 31, 2024. The Evergreen Shares are included in the 2020 Equity Incentive Plan share reserve as of September 30, 2025 as presented in the table above.

In August 2025, the Company awarded 300,000 shares of restricted stock units (“RSUs”) to a consultant in exchange for services to be provided, of which 150,000 were vested as of September 30, 2025 and 150,000 were unvested as of September 30, 2025. These shares of restricted common stock were issued pursuant to the Company’s 2020 Equity Incentive Plan. The fair value of these shares of restricted common stock was determined based on the share price of the Company as of the grant date, and was approximately \$0.2 million. As of September 30, 2025, the Company had unrecognized stock-based compensation expense of \$0.1 million, which is expected to be recognized over a weighted-average period of 0.25 years.

Stock-based Compensation Expense

The Company records stock-based compensation expense based on the fair value of stock options granted to employees, non-employee consultants and non-employee directors. During the three months ended September 30, 2025 and 2024, the Company recorded stock-based compensation expense of approximately \$0.5 million and \$0.3 million, respectively. During the nine months ended September 30, 2025 and 2024, the Company recorded stock-based compensation expense of approximately \$1.8 million and \$1.1 million, respectively. As of September 30, 2025, the Company had unrecognized stock-based compensation expense, excluding unrecognized stock compensation related to the unvested RSUs discussed above, of \$1.6 million, which is expected to be recognized over a weighted-average period of 1.5 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.

No options were granted in the three months ended September 30, 2025. The fair value of options granted during the nine months ended September 30, 2025 used the following weighted average assumptions and key inputs:

Black-Scholes-Merton Inputs

	Nine Months Ended September 30, 2025
Risk-free interest rate	4.39%
Expected term (in years)	5.40
Expected volatility	110.24%
Expected dividend yield	—%

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

Black-Scholes-Merton Inputs

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

The weighted average fair value of stock options granted for the nine months ended September 30, 2025 was \$1.46. The options have a contractual term of 10 years. The weighted average fair value of stock options granted during the three and nine months ended September 30, 2024, was \$0.99, in each period.

Activity under the Company's equity compensation plan for the nine months ended September 30, 2025 is as follows:

	Number of Options Outstanding	Weighted Average Exercise price per share	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Balance, December 31, 2024	2,559,440	\$ 4.07	8.88	\$ 683,016
Granted	919,750	1.77		
Expired/Cancelled	(350,000)	3.39		
Balance, September 30, 2025	<u>3,129,190</u>	<u>\$ 3.47</u>	<u>8.46</u>	<u>\$ —</u>
Options vested and exercisable at September 30, 2025	<u>2,258,559</u>	<u>\$ 3.89</u>	<u>8.27</u>	<u>\$ —</u>

For the three months ended September 30, 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 September 30,	
	2025	2024
Research and development	\$ 169,051	\$ 173,475
General and administrative	289,328	174,581
Total stock-based compensation expense	\$ 458,379	\$ 348,056

For the nine months ended September 30, 2025 and 2024, the amount of stock-based compensation expense included within research and development and general and administrative expenses was as follows:

	Nine Months Ended September 30,	
	2025	2024
Research and development	\$ 669,977	\$ 553,255
General and administrative	1,102,798	522,870
Total stock-based compensation expense	\$ 1,772,775	\$ 1,076,125

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 September 30, 2025 and 2024 was approximately \$13,800 and \$12,896, respectively. The operating lease cost on these leases for the nine months ended September 30, 2025 and 2024 was approximately \$41,400 and \$37,231, respectively.

Litigation

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

7. FAIR VALUE MEASUREMENTS

The following tables provide a summary of the assets and liabilities that are required to be measured at fair value on a recurring basis and where they are classified within the fair value hierarchy as of September 30, 2025 and December 31, 2024:

September 30, 2025				
	Level 1	Level 2	Level 3	Total
Assets:				
Money market funds (cash equivalents)	\$ 11,917,845	\$ —	\$ —	\$ 11,917,845
Total assets measured and recorded at fair value	<u>\$ 11,917,845</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 11,917,845</u>
Liabilities:				
Warrant liabilities	\$ —	\$ —	\$ 44,506	\$ 44,506
Total liabilities measured and recorded at fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 44,506</u>	<u>\$ 44,506</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 September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Balance, beginning of period	\$ 16,690	\$ 150,205	\$ 89,010	\$ 806,655
Change in fair value of warrant liabilities	27,816	(72,321)	(44,504)	(728,771)
Balance, end of period	<u>\$ 44,506</u>	<u>\$ 77,884</u>	<u>\$ 44,506</u>	<u>\$ 77,884</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 September 30, 2025 and December 31, 2024 as \$44,506 and \$89,010, respectively, using a Lattice model. The assumptions and key inputs used in the Lattice calculation were the following:

	September 30, 2025	December 31, 2024
Risk-free interest rate	4.07%	4.17%
Remaining expected term of Private Warrants	0.21	0.95
Expected volatility ⁽¹⁾	493.50%	128.70%
Stock price on valuation date	\$ 0.37	\$ 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, the Company's Chief Executive Officer, 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 and research and development expenses are used to allocate resources and are 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.

9. SUBSEQUENT EVENTS

October and November 2025 Warrant Exercises

In October and November 2025, the Company issued a total of 18,721,500 shares of common stock upon the exercise of 18,721,500 common stock warrants, with exercise prices ranging between \$0.335 and \$0.50 per common stock warrant, and resulting in gross proceeds of approximately \$6.4 million.

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 our 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 our 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 regain (as applicable) and maintain compliance with the continued listing requirements of The Nasdaq Capital Market and maintain the listing of our common stock 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, and on June 2, 2025, we announced a positive full dataset and successful completion of, our Phase 3 RECOVER open label extension (the “OLE” or the “OLE Trial”) a 1-year study evaluating the long-term safety, tolerability and efficacy of brilaroxazine in patients with schizophrenia. See “Recent Developments – Open Label Extension (OLE) Trial Results” below for information about the OLE Trial results, and our other filings from time to time with the SEC for more details on our brilaroxazine development program.

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. Brilaroxazine is a novel serotonin dopamine signaling modulator with multi-faceted direct and indirect activities on critical pathways implicated in 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 (n = 411) with schizophrenia and a mean PANSS total score of 97-99 at baseline include:

Primary and Secondary Endpoints	Point Reduction/ Improvement for Brilaroxazine 50 mg vs. Placebo at Week 4	Cohen's d Effect Size	P Value
PANSS Total Score	10.1	0.6	< 0.001
Positive Symptoms	2.8	0.5	< 0.001
PANSS Excitement/Agitation	2.1	0.5	< 0.001
Negative Symptoms (NS)	2	0.4	0.003
NS Marder Factor	2.1	0.4	0.002
PANSS Social Cognition	1.6	0.5	< 0.001
Personal & Social Performance	6.3	0.5	< 0.001
CGI-S Score	0.5 (≥ 1 point in 78% of patients)	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).

Open Label Extension (OLE) Trial Results

On June 2, 2025, we announced a positive full dataset and successful completion of our Phase 3 RECOVER open-label extension (OLE) 1-year study evaluating the long-term safety, tolerability and efficacy of brilaroxazine in patients with schizophrenia. Once daily brilaroxazine led to robust broad-spectrum efficacy that was sustained over 1-year and was generally well tolerated with a discontinuation rate of 35% in this long-term study.

We announced the full data of the Phase 3 RECOVER trial OLE on June 2, 2025 and summarized herein are the results:

- 446 patients enrolled in the OLE trial
- 159 patients completed 1-year (12 months) of treatment
- 303 patients 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

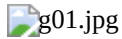
Key efficacy, biomarkers and compliance results for pooled analysis of brilaroxazine 15, 30, and 50 mg over 1 year treatment in RECOVER trial OLE (N=446)



Key safety and tolerability results for pooled analysis of brilaroxazine 15, 30, and 50 mg over 1 year treatment in RECOVER trial OLE (N=446)



Brilaroxazine: Strong Efficacy & Well-Tolerated Safety with Low Discontinuation Over 1-Year RECOVER Phase 3 trials in acute and stable schizophrenia patients (total patients enrolled, N=857)



Ongoing clinical activities related to closing the OLE trial involve closeout of clinical sites globally and preparation of the RECOVER study report, with such activities currently in progress.

Potential Path to NDA Submission

In addition to the successfully completed Phase 3 RECOVER-1 and OLE trials, we also have positive data from the Phase 2 REFRESH trial. Our original clinical development plan called for a second, larger, Phase 3 trial identified as RECOVER-2. However, given the quantity and quality of positive data we have gathered so far on the use of brilaroxazine to treat acute schizophrenia, we believe that we have met the statutory clinical data requirement needed for NDA submission and approval. We therefore have a planned meeting with the FDA in Q4-2025 to discuss the submission of an NDA based solely on the data gathered to date. If the FDA response is positive, we will target NDA submission in Q2-2026.

May 2025 ATM Sales Agreement

On May 30, 2025, we entered into an at market issuance sales agreement (the “May 2025 ATM Sales Agreement”) with B. Riley Securities, Inc. and Alliance Global Partners serving as agents (the “Agents”), with respect to an at-the-market (ATM) offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$50 million through the Agents. During the three months ended September 30, 2025, we sold 1,183,506 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of approximately \$0.5 million after deducting sales agent commissions and other offering expenses of approximately \$30.8 thousand. During the nine months ended September 30, 2025, we sold 2,447,170 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of \$1.2 million after deducting sales agent commissions and other offering expenses of approximately \$0.4 million.

June 2025 Public Offering

On June 26, 2025, we entered into a placement agency agreement (the “June 2025 Placement Agency Agreement”) with A.G.P./Alliance Global Partners, as the placement agent (the “Placement Agent”), pursuant to which we sold in a public offering (i) an aggregate of 20,000,000 shares of our common stock, (ii) Series C warrants exercisable for an aggregate of up to 20,000,000 shares of common stock (the “Series C Common Warrants”) and (iii) Series D warrants exercisable for an aggregate of up to 20,000,000 shares of common stock (the “Series D Common Warrants” and together with the Series C Common Warrants, the “June 2025 Warrants”), for aggregate gross proceeds of \$10.0 million (the “June 2025 Public Offering”). Each share of common stock was sold together with (i) a Series C Common Warrant to purchase one share of common stock and (ii) a Series D Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.50 per share of common stock and accompanying June 2025 Warrants. The Series C Common Warrants are exercisable immediately upon issuance, have a term of five years from the date of issuance and have an exercise price of \$0.50 per share. The Series D Common Warrants are exercisable immediately upon issuance, have a term of twelve months from the date of issuance and have an exercise price of \$0.50 per share. The net proceeds to us from the June 2025 Public Offering were approximately \$9.0 million, after deducting Placement Agent fees and expenses and other offering expenses payable by us.

September 2025 Public Offering

On September 18, 2025, we entered into a placement agency agreement (the “September 2025 Placement Agency Agreement”) with A.G.P./Alliance Global Partners, as the placement agent (the “Placement Agent”), relating to the offering, issuance and sale of (i) an aggregate of 27,000,000 shares of our common stock, (ii) Series E warrants exercisable for an aggregate of up to 27,000,000 shares of common stock (the “Series E Common Warrants”) and (iii) Series F warrants exercisable for an aggregate of up to 27,000,000 shares of common stock (the “Series F Common Warrants” and together with the Series E Common Warrants, the “September 2025 Warrants”), for aggregate gross proceeds of \$9.0 million (the “September 2025 Offering”). Each share of common stock was sold together with (i) a Series E Common Warrant to purchase one share of common stock and (ii) a Series F Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.335 per share of common stock and accompanying Common Warrants. The Series E Common Warrants are exercisable immediately, will have a term of five years from the date of issuance and have an exercise price of \$0.335 per share. The Series F Common Warrants are exercisable immediately, will have a term of twelve months and have an exercise price of \$0.335 per share. The net proceeds to us from the September 2025 Public Offering were approximately \$8.1 million, after deducting Placement Agent fees and expenses and other offering expenses payable by us.

One Big Beautiful Bill Act

On July 4, 2025, the One Big Beautiful Bill Act (the “Act”) was signed into law. The Act makes permanent key elements of the Tax Cuts and Jobs Act, including 100% bonus depreciation, domestic research cost expensing, and the business interest expense limitation. We are currently evaluating the impact of the Act on our consolidated financial statements.

Intellectual Property Overview

We are the sole owner of our 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 November 6, 2025 our portfolio of intellectual property consists of 72 granted patents and 25 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 the U.S. 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 Colombia. We believe that our patent portfolio provides good protection of brilaroxazine. All of the U.S. 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 U.S. original brilaroxazine patent may be extendable up to 2035.

We also own additional brilaroxazine granted patents and pending patent applications for additional indications. We own attention hyperactivity disorder patents in the U.S., which will expire in 2035. We own pulmonary arterial hypertension patents in the U.S., Europe, China, Japan, and Hong Kong; all of which will expire in 2036. We own pulmonary fibrosis patents in the U.S., China, Japan, and Hong Kong, and pending applications in Brazil and Europe, which are all expected to expire in 2038.

We have one family of pending applications directed to a formulation of brilaroxazine, which are filed in Brazil, Canada, China, Europe, India, Japan, Korea, Mexico, and the U.S.

We have one family of pending applications directed to a method of using brilaroxazine for treating psoriasis, which are filed in Brazil, Canada, China, Europe, Japan, Korea, Mexico, and the U.S.

We have one U.S. pending application directed to a brilaroxazine composition.

We also have three U.S. provisional applications pending: one directed to using brilaroxazine for treating a specific symptom, and two 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 September 30, 2025, we had a working capital surplus of approximately \$3.8 million, an accumulated deficit of \$180.8 million and cash and cash equivalents on hand of approximately \$13.2 million. Our net loss for the three months ended September 30, 2025 and 2024, was approximately \$4.0 million and \$8.4 million, respectively. Our net loss for the nine months ended September 30, 2025 and 2024, was approximately \$16.5 million and \$23.7 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 Part II, Item 9A of our fiscal year 2024 Annual Report on Form 10-K, and in this Quarterly Report on Form 10-Q below in Part I, 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 a potential Phase 3 RECOVER-2 Trial, if required, 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 Part II, Item 9A of our fiscal year 2024 Annual Report on Form 10-K, and in this Quarterly Report on Form 10-Q below in Part I, Item 4. Controls and Procedures.

In light of successful completion of the Phase 3 RECOVER-1 trial, a second large randomized double-blind trial (Phase 2 REFRESH) and a large Phase 3 RECOVER OLE trial to assess long-term safety, tolerability, sustainable efficacy and treatment adherence, we are currently assessing appropriate next steps in brilaroxazine's path to approval. See "*Research and Development Expenses*" below.

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 and successful completion of the OLE announced in June 2025 - Planned meeting with FDA in Q4-2025 to discuss the submission of NDA based solely on the data gathered to date. If the FDA response is positive, we will target NDA submission in Q2-2026.*
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.

* Potential Phase 3 RECOVER-2 Trial intended initiation in early 2026, if such trial is required pending planned meeting with FDA and agency's recommendation for brilaroxazine's path to approval.

** 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 remaining OLE activities and study wrap-up and our potential Phase 3 RECOVER-2 Trial, if required, 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 (with our estimates including, for these purposes, expected costs of our potential Phase 3 RECOVER-2 Trial, if required), may total approximately \$60 million over the next approximately two years, consisting of our estimated costs for (i) remaining OLE activities and wrap-up, (ii) our potential Phase 3 RECOVER-2 Trial, if required, and additional activities supporting the brilaroxazine program through the planned NDA submission, and (iii) additional Research & Development costs (primarily associated with consulting, scientific, research and other expenses in support of remaining OLE activities and wrap-up and our potential Phase 3 RECOVER-2 Trial, if required, 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 potential Phase 3 RECOVER-2 Trial, if required, and remaining OLE activities and wrap-up 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. We believe we have successfully completed with positive results the two randomized double blind trials, as well as the safety, pharmacology and non-clinical studies typically required for NDA approval. We therefore are preparing to meet with FDA to gain alignment on our path to NDA submission, including a discussion of whether there is a need for a second phase 3 study (RECOVER-2). If FDA tells us we need to initiate a second phase 3 study, we intend to commence it in early 2026, subject to financing. As stated previously, there are numerous risks and uncertainties associated with developing our therapeutics, including:

- 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;
- our ability to raise capital to finance our clinical trials; 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 September 30, 2025 and 2024:

The following table summarizes our results of operations for the three months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Change Amount	Change Percentage
	2025	2024		
Operating expenses				
Research and development	\$ 2,131,444	\$ 6,858,285	\$ (4,726,841)	(68.9)%
General and administrative	1,898,397	1,604,249	294,148	18.3%
Total operating expenses	4,029,841	8,462,534		
Loss from operations	(4,029,841)	(8,462,534)		
(Loss) gain on remeasurement of warrant liabilities	(27,816)	72,321	(100,137)	(138.5)%
Interest expense	(2,605)	(5,146)	2,541	(49.4)%
Interest income	59,103	53,248	5,855	11.0%
Other expense, net	(6,774)	(23,687)	16,913	(71.4)%
Total other income, net	21,908	96,736		
Loss before provision for income taxes	(4,007,933)	(8,365,798)		
Provision for income taxes	2,840	—	2,840	100.0%
Net loss	\$ (4,010,773)	\$ (8,365,798)		

Research and Development Expenses

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

For the three months ended September 30, 2025 and 2024, research and development expenses were approximately \$2.1 million and \$6.9 million, respectively. Specifically, during the three months ended September 30, 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 \$0.5 million and \$0.4 million, respectively (ii) internal stock-based compensation expenses with respect to employees involved in research and development activities of approximately \$0.2 million and \$0.3 million, respectively; and (iii) external research and development expenses of approximately \$1.4 million and \$6.2 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately \$1.2 million and \$5.6 million, respectively, non-clinical safety related costs of \$0.1 million and \$0.4 million, respectively, non-clinical manufacturing related costs of approximately \$0.1 million and \$0.2 million, respectively).

The decrease in research and development expenses for the three months ended September 30, 2025 as compared to the three months ended September 30, 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 proceeded toward completion during the 2025 period with remaining OLE activities thereafter consisting of post-data readout activities and trial wind-down matters.

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 OLE Trial remaining activities and associated expenses and increased expenses associated with our potential Phase 3 RECOVER-2 Trial, if required, to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. For additional information, please see the discussion appearing above in the introductory section of this Part I-Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

General and Administrative Expenses

For the three months ended September 30, 2025 and 2024, general and administrative expenses were approximately \$1.9 million and \$1.6 million, respectively. Specifically, during the three months ended September 30, 2025 and 2024, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately \$0.3 million and \$0.2 million, respectively; (ii) consultant and professional expenses of approximately \$0.4 million and \$0.6 million, respectively; (iii) legal expenses of approximately \$0.5 million and \$0.2 million, respectively; (iv) employee related expenses of approximately \$0.5 million and \$0.4 million, respectively; (v) D&O insurance expenses of approximately \$0.1 million in both periods; and (vi) other general and administrative expenses of approximately \$0.1 million in both periods.

(Loss) Gain on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities loss of approximately \$27.8 thousand for the three months ended September 30, 2025 resulting from the increase in the calculated fair value of the warrants attributed to an increase in volatility offset by a marginal decrease in stock price. For the three months ended September 30, 2024, we recognized a remeasurement of warrant liabilities gain of approximately \$72.3 thousand due to the decrease in the calculated fair value of the warrants attributed to a decrease in volatility.

Interest Expense

We incurred interest expense of approximately \$2.6 thousand and \$5.1 thousand for the three months ended September 30, 2025 and 2024, respectively. The decrease in interest expense was primarily caused by a decrease in the corresponding short-term debt balance for the period.

Interest Income

Interest income was approximately \$59.1 thousand and \$53.2 thousand for the three months ended September 30, 2025 and 2024, respectively. Interest income increased by \$5.9 thousand primarily due to the average higher cash and cash equivalents daily balance for the three months ended September 30, 2025 compared to the three months ended September 30, 2024.

Other Expense, net

Other expense, net was approximately \$6.8 thousand for the three months ended September 30, 2025 and approximately \$23.7 thousand for the three months ended September 30, 2024. The decrease of approximately \$16.9 thousand was primarily attributable to a lower period-over-period foreign currency transaction loss from favorable foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Comparison of the nine months ended September 30, 2025 and 2024:

The following table summarizes our results of operations for the nine months ended September 30, 2025 and 2024:

	Nine Months Ended September 30,		Change Amount	Change Percentage
	2025	2024		
Operating expenses				
Research and development	\$ 9,969,736	\$ 18,226,497	\$ (8,256,761)	(45.3)%
General and administrative	6,671,254	6,287,786	383,468	6.1%
Total operating expenses	16,640,990	24,514,283		
Loss from operations	(16,640,990)	(24,514,283)		
Gain on remeasurement of warrant liabilities	44,504	728,771	(684,267)	(93.9)%
Interest expense	(19,022)	(13,786)	(5,236)	38.0%
Interest income	168,061	313,956	(145,895)	(46.5)%
Other expense, net	(33,769)	(159,202)	125,433	(78.8)%
Total other income, net	159,774	869,739		
Loss before provision for income taxes	(16,481,216)	(23,644,544)		
Provision for income taxes	16,007	14,781	1,226	8.3%
Net loss	<u>\$(16,497,223)</u>	<u>\$(23,659,325)</u>		

Research and Development Expenses

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

For the nine months ended September 30, 2025 and 2024, research and development expenses were approximately \$10.0 million and \$18.2 million, respectively. Specifically, during the nine months ended September 30, 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 \$2.0 million and \$1.9 million, respectively; (ii) internal stock-based compensation expenses with respect to employees involved in research and development activities, of approximately \$0.7 million and \$0.6 million, respectively; and (iii) external research and development expenses of approximately \$7.3 million and \$15.7 million, respectively (which includes clinical (including clinical consulting) research and development costs of approximately \$6.0 million and \$12.6 million, respectively, non-clinical safety related costs of approximately \$0.7 million and \$0.8 million, respectively, non-clinical manufacturing related costs of approximately \$0.5 million and \$2.0 million, respectively, and non-clinical consulting and other related costs of approximately \$0.1 million and \$0.3 million, respectively).

The decrease in research and development expenses for the nine months ended September 30, 2025 as compared to the nine months ended September 30, 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 proceeded toward completion during the 2025 period with remaining OLE activities thereafter consisting of post-data readout activities and trial wind-down matters.

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 OLE Trial remaining activities and associated expenses and increased expenses associated with our potential Phase 3 RECOVER-2 Trial, if required, to take us through the submission of the planned NDA for brilaroxazine, together with additional costs post-NDA submission in preparation of potential commercialization if approved. For additional information, please see the discussion appearing above in the introductory section of this Part I-Item 2, Management's Discussion and Analysis of Financial Condition and Results of Operations.

General and Administrative Expenses

For the nine months ended September 30, 2025 and 2024, general and administrative expenses were approximately \$6.7 million and \$6.3 million, respectively. Specifically, during the nine months ended September 30, 2025 and 2024, our general and administrative expenses consisted primarily of: (i) stock-based compensation expense of approximately \$1.1 million and \$0.5 million, respectively; (ii) consultant and professional expenses of approximately \$2.3 million and \$2.7 million, respectively; (iii) legal expenses of approximately \$1.2 million and \$1.0 million, respectively; (iv) employee related expenses of approximately \$1.5 million and \$1.4 million, respectively; (v) Directors and Officers insurance expenses of approximately \$0.3 million and \$0.4 million, respectively; and (vi) other general and administrative expenses of approximately \$0.3 million in both periods.

Gain on Remeasurement of Warrant Liabilities

We recognized a remeasurement of warrant liabilities gain of approximately \$44.5 thousand and \$728.8 thousand for the nine months ended September 30, 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 \$19.0 thousand and \$13.8 thousand for the nine months ended September 30, 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 \$0.2 million and \$0.3 million for the nine months ended September 30, 2025 and 2024, respectively. The interest income decrease of approximately \$0.1 million was primarily due to the average lower cash and cash equivalents daily balance for the nine months ended September 30, 2025 compared to the nine months ended September 30, 2024.

Other Expense, net

Other expense, net was approximately \$33.8 thousand for the nine months ended September 30, 2025 and approximately \$159.2 thousand for the nine months ended September 30, 2024. The decrease of approximately \$125.4 thousand was primarily attributable to a lower period-over-period foreign currency transaction loss from foreign currency fluctuations related to the consolidation of the Company's Indian subsidiary.

Liquidity and Capital Resources

	September 30, 2025	December 31, 2024	Change Amount	Percentage
Balance Sheet Data:				
Cash and cash equivalents	\$ 13,183,259	\$ 13,476,331	\$ (293,072)	(2.2)%
Working capital surplus	3,774,520	81,861	3,692,659	4510.9%
Total assets	14,332,649	15,503,088	(1,170,439)	(7.5)%
Total stockholders' equity	4,549,735	812,572	3,737,163	459.9%

	Nine Months Ended September 30,		Change Amount	Percentage
	2025	2024		
Statement of Cash Flow Data:				
Net cash used in operating activities	\$(18,796,432)	\$(24,443,419)	\$ 5,646,987	(23.1)%
Net cash provided by financing activities	18,503,360	6,634,780	11,868,580	178.9%
Net decrease in cash and cash equivalents	<u>\$ (293,072)</u>	<u>\$(17,808,639)</u>	<u>\$ 17,515,567</u>	<u>(98.4)%</u>

Capital Resources

We have funded our operations to date primarily from the issuance and sale of our equity and convertible equity securities. As of September 30, 2025, we had cash and cash equivalents of approximately \$13.2 million. To fund our current operating plans, we will need to raise significant additional capital. Our existing cash and cash equivalents will not be sufficient for us to complete development of our product candidates and, if applicable, to prepare for commercializing any product candidate that may receive approval. Accordingly, we will continue to require substantial additional capital beyond our existing cash to continue our clinical development and potential commercialization activities. We believe that we have adequate cash on hand to cover anticipated outlays into the second quarter of 2026 but will need additional fundraising activities and cash on hand during the 2026 fiscal year. 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. Without limiting the foregoing, we may issue shares of common stock from time to time pursuant to our May 2025 ATM Sales Agreement (please see further discussion in this section below). 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.

On May 30, 2025, we entered into an at the May 2025 ATM Sales Agreement with the Agents, with respect to an at-the-market (ATM) offering program under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$50 million through the Agents. During the three months ended September 30, 2025, we sold 1,183,506 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of \$0.5 million after deducting sales agent commissions and other offering expenses of approximately \$30.8 thousand. During the nine months ended September 30, 2025, we sold 2,447,170 shares of common stock pursuant to the May 2025 ATM Sales Agreement for net proceeds of \$1.2 million after deducting sales agent commissions and other offering expenses of approximately \$0.4 million.

On June 26, 2025, we entered into the June 2025 Placement Agency Agreement with the Placement Agent, relating to the offering, issuance and sale in a public offering of (i) an aggregate of 20,000,000 shares of our common stock, (ii) Series C Warrants exercisable for an aggregate of up to 20,000,000 shares of common stock and (iii) Series D Warrants exercisable for an aggregate of up to 20,000,000 shares of common stock, for aggregate gross proceeds of \$10.0 million. Each share of common stock was sold together with (i) a Series C Common Warrant to purchase one share of common stock and (ii) a Series D Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.50 per share of common stock and accompanying June 2025 Warrants. The Series C Common Warrants are exercisable immediately upon issuance, have a term of five years from the date of issuance and have an exercise price of \$0.50 per share. The Series D Common Warrants are exercisable immediately upon issuance, have a term of twelve months from the date of issuance and have an exercise price of \$0.50 per share. The net proceeds to us from the June 2025 Public Offering were approximately \$9.0 million, after deducting Placement Agent fees and expenses and other offering expenses payable by us.

On September 18, 2025, we entered into the September 2025 Placement Agency Agreement with the Placement Agent, relating to the offering, issuance and sale of (i) an aggregate of 27,000,000 shares of our common stock, (ii) Series E Common Warrants exercisable for an aggregate of up to 27,000,000 shares of our common stock and (iii) Series F Common Warrants exercisable for an aggregate of up to 27,000,000 shares of common stock, for aggregate gross proceeds of \$9.0 million. Each share of common stock was sold together with (i) a Series E Common Warrant to purchase one share of common stock and (ii) a Series F Common Warrant to purchase one share of common stock, at a combined public offering price of \$0.335 per share of common stock and accompanying Common Warrants. The Series E Common Warrants are exercisable immediately, have a term of five years from the date of issuance and have an exercise price of \$0.335 per share. The Series F Common Warrants are exercisable immediately, have a term of twelve months and have an exercise price of \$0.335 per share. The net proceeds to us from the September 2025 Public Offering were approximately \$8.1 million, after deducting Placement Agent fees and expenses and other offering expenses payable by us.

During the nine months ended September 30, 2025, an aggregate of 160,750 of the common stock warrants, issued in our December 2024 financing were 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 nine months ended September 30, 2025 was approximately \$18.8 million, consisting primarily of a net loss of approximately \$16.5 million, adjusted for non-cash items, including stock-based compensation expense of approximately \$1.8 million, coupled with a decrease in our operating assets and liabilities totaling approximately \$4.0 million. The \$4.0 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 net with a decrease in prepaid expenses and other current assets and a decrease in prepaid clinical trial costs.

Net cash used in operating activities for the nine months ended September 30, 2024, was approximately \$24.4 million, consisting primarily of a net loss of approximately \$23.7 million, adjusted for non-cash items, including a change in fair value of warrant liabilities gain of approximately \$0.7 million, and partially offset by stock-based compensation expense of approximately \$1.1 million, coupled with a decrease in our operating assets and liabilities totaling approximately \$1.1 million. The \$1.1 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 nine months ended September 30, 2025 was approximately \$18.5 million. Cash provided by financing activities during the nine months ended September 30, 2025 was attributable to (i) \$19.0 million in gross proceeds from the sale of common stock, Series C Common Warrants and Series D Common Warrants in our June 2025 Public Offering and Series E Common Warrants and Series F Common Warrants in our September 2025 Public Offering, partially offset by transaction costs of approximately \$1.9 million, approximately \$0.4 million of which was not yet paid as of September 30, 2025; (ii) gross proceeds of approximately \$1.6 million from the sale of common stock under our May 2025 ATM Sales Agreement, partially offset by transaction costs of approximately \$0.4 million, approximately \$0.1 million of which was not yet paid as of September 30, 2025; and (iii) approximately \$0.2 million in proceeds from the exercise of common stock warrants. The foregoing were partially offset by repayments on the short-term debt of approximately \$0.5 million.

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

Off-Balance Sheet Arrangements

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

As required by Rule 13a-15(b) under the Exchange Act, our management, under the supervision and with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and 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 September 30, 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 September 30, 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.

We are currently listed on The Nasdaq Capital Market. 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 a notice from Nasdaq indicating that we are not in compliance with the requirement under Nasdaq Listing Rule 5550(a)(2) to maintain a minimum bid price of \$1.00 per share for continued listing on Nasdaq (the "Bid Price Requirement"). We were provided a compliance period of 180 calendar days from the date of the notice, or until November 10, 2025, to regain compliance with the Bid Price Requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). On November 11, 2025, we received a letter from Nasdaq indicating that, based upon our not having regained compliance with the Bid Price Requirement and our ineligibility for a second 180 calendar day compliance period, the Listing Qualifications Staff of Nasdaq had determined to delist the Company's securities from Nasdaq unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). We intend to timely request a hearing before the Panel, at which hearing we will request an extension within which to evidence compliance with all applicable requirements for continued listing on Nasdaq, including compliance with the Bid Price Requirement. Our request for a hearing will stay any suspension or delisting action by the Staff pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. We intend to continue to take definitive steps in an effort to evidence compliance with the Bid Price Requirement; however, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the Bid Price Requirement within any extension period that may be granted by the Panel.

We will continue to monitor the closing bid price of our common stock and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the Bid Price Requirement. If we seek to 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 and/or warrants.

We must regain compliance with Nasdaq's 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.

Disruptions at the FDA and other government agencies caused by funding shortages could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times - including the most recent shutdown, which began October 1, 2025 and continued until November 12, 2025 – and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Except as previously reported, 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 Delisting or Failure to Satisfy a Continued Listing Rule or Standard

On November 11, 2025, we received a letter (the "Letter") from the Listing Qualifications Staff (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that, because we have not regained compliance with the \$1.00 minimum bid price requirement set forth in Nasdaq Listing Rule 5550(a)(2) for continued listing on The Nasdaq Capital Market (the "Bid Price Requirement") and our ineligibility for a second 180 calendar day compliance period, the Staff had determined to delist our securities from Nasdaq unless we timely request a hearing before the Nasdaq Hearings Panel (the "Panel"). The Bid Price Requirement of the Nasdaq Listing Rules requires listed securities to maintain a minimum bid price of \$1.00 per share and, as previously disclosed, on May 13, 2025, Nasdaq had notified us that based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the Bid Price Requirement. In accordance with Listing Rule 5810(c)(3)(A), Nasdaq had provided us 180 calendar days, or until November 10, 2025, to regain compliance with the Bid Price Requirement. We have not regained compliance with the Bid Price Requirement during such 180 calendar day period and, because we do not meet Nasdaq's \$5,000,000 minimum stockholders' equity initial listing requirement, nor do we qualify under any of the initial listing alternatives, the Staff determined that we were not eligible for an additional 180-day extension to meet the Bid Price Requirement.

We fully intend to timely request a hearing before the Panel, at which hearing we will request an extension within which to evidence compliance with the Bid Price Requirement. Our request for a hearing will stay any suspension or delisting action by the Staff pending the hearing and the expiration of any additional extension period granted by the Panel following the hearing. We intend to continue to take definitive steps in an effort to evidence compliance with the Bid Price Requirement, including by effecting a reverse stock split, if necessary. However, there can be no assurance that the Panel will grant our request for continued listing or that we will be able to evidence compliance with the Bid Price Requirement within any extension period that may be granted by the Panel or maintain compliance with the other Nasdaq listing requirements.

We, by filing this disclosure in this Item 5 of Part II of this Form 10-Q, disclose our receipt of the Letter from Nasdaq in accordance with Nasdaq Listing Rule 5810(b).

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

During the fiscal quarter ended September 30, 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
3.1	<u>Bylaws of Reviva Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the Company’s Current Report on Form 8-K filed with the SEC on December 14, 2020).</u>
3.2	<u>Amendment No. 1, as adopted and approved by the Board of Directors on September 26, 2025, to the Bylaws of Reviva Pharmaceuticals Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the Company’s Current Report on Form 8-K filed with the SEC on September 26, 2025).</u>
4.1	<u>Form of Series E Warrant (incorporated by reference to Exhibit 4.1 to the Company’s Current Report on Form 8-K filed with the SEC on September 19, 2025).</u>
4.2	<u>Form of Series F Warrant (incorporated by reference to Exhibit 4.2 to the Company’s Current Report on Form 8-K filed with the SEC on September 19, 2025).</u>
10.1	<u>Form of Securities Purchase Agreement from September 2025 Public Offering (incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed with the SEC on September 19, 2025).</u>
10.2	<u>Placement Agency Agreement, dated September 18, 2025, between Reviva Pharmaceuticals Holdings, Inc. and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed with the SEC on September 19, 2025).</u>
31.1*	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)</u>
31.2*	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a)</u>
32.1**	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350</u>
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: November 13, 2025

By: /s/ Laxminarayan Bhat

Laxminarayan Bhat
Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 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: November 13, 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;
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 13, 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 September 30, 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, 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 13th day of November, 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.