

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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **August 14, 2025**

REVIVA PHARMACEUTICALS HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38634

(Commission File Number)

85-4306526

(IRS Employer
Identification No.)

10080 N Wolfe Road, Suite SW3-200, Cupertino, CA

(Address of principal executive offices)

95014

(Zip Code)

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

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02. Results of Operations and Financial Condition.

Reviva Pharmaceuticals Holdings, Inc. (the "Company") issued a press release on August 14, 2025, disclosing financial information and operating metrics for its fiscal quarter ended June 30, 2025 and discussing its business outlook. A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 7.01. Regulation FD Disclosure.

See "Item 2.02 Results of Operations and Financial Condition" above.

The information in this Current Report on Form 8-K under Items 2.02 and 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following Exhibit 99.1 is furnished with this report:

Exhibit No.	Description
99.1	Press Release issued by Reviva Pharmaceuticals Holdings, Inc., dated August 14, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 hereunto duly authorized.

REVIVA PHARMACEUTICALS HOLDINGS, INC.

Dated: August 14, 2025

By: /s/ Narayan Prabhu
Name: Narayan Prabhu
Title: Chief Financial Officer

Reviva Reports Second Quarter 2025 Financial Results and Recent Business Highlights

- Well-tolerated safety profile and robust broad-spectrum efficacy sustained over 1-year across all symptom domains including negative symptoms in open label extension (OLE) 1-year trial –
- Successful completion of two large randomized double-blind clinical trials, including one Phase 2 and one Phase 3 trial, a 1-year OLE trial, and clinical pharmacology studies designed to support filing of New Drug Application (NDA) –
- Planned meeting with Food and Drug Administration (FDA) to discuss brilaroxazine's path to approval for schizophrenia in Q4 2025; potential NDA submission targeted for Q2 2026 –

Cupertino, Calif., August 14, 2025 – Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) ("Reviva" or the "Company"), a late-stage pharmaceutical company developing therapies that seek to address unmet medical needs in the areas of central nervous system (CNS), inflammatory and cardiometabolic diseases, today reported financial results for the second quarter ended June 30, 2025 and summarized recent business highlights.

"The successful completion of our global OLE 1-year trial marks a major milestone for the brilaroxazine program as we advance toward potential registration," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "This comprehensive dataset reinforces our prior positive clinical results and highlights the long-term safety, broad-spectrum sustained efficacy, and strong adherence profile of once daily brilaroxazine. We believe all key clinical data required for NDA are completed and we are preparing for an End-of-Phase 3 meeting with the FDA planned in the fourth quarter of the year to discuss our future NDA submission based on the current data package and excluding the planned Phase 3 RECOVER-2 trial. Pending favorable feedback from the FDA, we will target an NDA submission in the second quarter of 2026. Brilaroxazine continues to demonstrate a differentiated and durable clinical profile, positioning it as a potential new standard of care in schizophrenia and a meaningful driver of long-term value."

Second Quarter 2025 and Recent Business Highlights

Clinical Program and Business Highlights

- Announced a positive full dataset and successful completion of the Company's Phase 3 RECOVER open-label extension (OLE) 1-year study evaluating the long-term safety, tolerability and efficacy of brilaroxazine in patients with schizophrenia
 - o Once daily brilaroxazine (pooled 15, 30, and 50 mg, N=446) led to robust broad-spectrum efficacy that was sustained over 1-year including PANSS total score (-18.1), positive symptoms (-5.0), negative symptoms (-4.4) and negative Marder factor (-4.4)
 - o Generally well tolerated with a discontinuation rate of 35% after 1-year for pooled doses of brilaroxazine (pooled 15, 30, and 50 mg, N=446)
 - Continuing efforts aimed at expansion of strong diversified patent portfolio comprising composition of matter and lifecycle management strategies for innovative formulations and method of treatment for different major indications with clear regulatory path including potential patent and/or market exclusivity up to 2045 and beyond.
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- Presented a late-breaking poster presentation on the RECOVER 12-month OLE trial for brilaroxazine in schizophrenia at the 2025 American Society of Clinical Psychopharmacology (ASCP) annual meeting on Wednesday May 28, 2025, in Scottsdale, AZ.
- Completed public equity offering raising gross proceeds of \$10.0 million, before deducting placement agent fees and other offering expenses.

Anticipated Milestones and Events

- Planned meeting with FDA to discuss brilaroxazine's path to approval in Q4 2025
- Potential NDA submission for brilaroxazine in schizophrenia targeted in Q2 2026
- Plans are being assessed to initiate a potential registrational Phase 3 RECOVER-2 trial evaluating brilaroxazine for the treatment of schizophrenia pending FDA recommendation for a path to approval
- Investigational new drug application (IND) submission for liposomal-gel formulation of brilaroxazine in psoriasis expected by Q2- 2026
- Pursuing partnership opportunities for the development of our pipeline

Financial Results for June 30, 2025

- The Company reported a net loss of approximately \$6.1 million, or \$0.12 per share, for the three months ended June 30, 2025, compared to a net loss of approximately \$7.9 million, or \$0.26 per share, for the three months ended June 30, 2024.
- As of June 30, 2025, the Company's cash and cash equivalents totaled approximately \$10.4 million compared to approximately \$13.5 million as of December 31, 2024.

About Reviva

Reviva is a late-stage biopharmaceutical company that discovers, develops, and seeks to commercialize next-generation therapeutics for diseases representing unmet medical needs and burdens to society, patients, and their families. Reviva's current pipeline focuses on the central nervous system (CNS), inflammatory and cardiometabolic diseases. Reviva's pipeline currently includes two drug candidates, brilaroxazine (RP5063) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both brilaroxazine and RP1208 in the United States, Europe, and several other countries.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act, as amended, including those relating to the Company's plans for its brilaroxazine program including intended steps towards potential approval, the Company's plans for meeting with FDA and plans for potential NDA submission, the Company's statements regarding assessment of plans for a potential registrational Phase 3 RECOVER-2 trial evaluating brilaroxazine for the treatment of schizophrenia, if required, statements about potential IND submissions, the Company's expectations regarding the anticipated clinical profile of its product candidates, including statements regarding anticipated efficacy or safety profile, and those relating to the Company's expectations, intentions or beliefs regarding matters including product development and clinical trial plans and the timing thereof, including the anticipated timing of the availability of trial data, clinical and regulatory timelines and expenses, planned or intended additional trials or studies and the timing thereof, planned or intended regulatory submissions and the timing thereof, trial results, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential opportunities for development including partnerships, growth or expansion opportunities and other statements that are predictive in nature. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management's current beliefs and assumptions.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expect," "anticipate," "intend," "plan," "believe," "estimate," "potential," "predict," "project," "should," "would" and similar expressions and the negatives of those terms. These statements relate to future events or our financial performance and involve known and unknown risks, uncertainties, and other factors which may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such factors include those set forth in the Company's most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2024, and the Company's other filings from time to time with the Securities and Exchange Commission. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this press release. The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

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REVIVA PHARMACEUTICALS HOLDINGS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	June 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	\$ 10,363,714	\$ 13,476,331
Prepaid clinical trial costs	104,447	540,601
Prepaid expenses and other current assets	346,964	666,435
Total current assets	10,815,125	14,683,367
Non-current prepaid clinical trial costs	819,721	819,721
Total Assets	\$ 11,634,846	\$ 15,503,088
Liabilities and Stockholders' Equity (Deficit)		
Liabilities		
Short-term debt	\$ 113,246	\$ 458,154
Accounts payable	4,968,688	6,283,430
Accrued clinical expenses	5,470,185	6,723,719
Accrued compensation	602,592	635,587
Other accrued liabilities	922,592	500,616
Total current liabilities	12,077,303	14,601,506
Warrant liabilities	16,690	89,010
Total Liabilities	12,093,993	14,690,516
Commitments and contingencies		
Stockholders' Equity (Deficit)		
Common stock, par value of \$0.0001; 315,000,000 shares authorized; 68,003,613 and 46,579,199 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	6,800	4,658
Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2025 and December 31, 2024	—	—
Additional paid-in capital	176,293,553	165,080,964
Accumulated deficit	(176,759,500)	(164,273,050)
Total stockholders' equity (deficit)	(459,147)	812,572
Total Liabilities and Stockholders' Equity (Deficit)	\$ 11,634,846	\$ 15,503,088

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Operating expenses				
Research and development	\$ 3,724,755	\$ 5,584,347	\$ 7,838,292	\$ 11,368,212
General and administrative	2,348,227	2,545,296	4,772,857	4,683,537
Total operating expenses	<u>6,072,982</u>	<u>8,129,643</u>	<u>12,611,149</u>	<u>16,051,749</u>
Loss from operations	(6,072,982)	(8,129,643)	(12,611,149)	(16,051,749)
Other income (expense)				
Gain on remeasurement of warrant liabilities	11,126	200,273	72,320	656,450
Interest expense	(4,797)	(5,153)	(16,417)	(8,640)
Interest income	22,847	87,610	108,958	260,708
Other (expense) income, net	(1,850)	(5,621)	(26,995)	(135,515)
Total other (expense) income, net	<u>27,326</u>	<u>277,109</u>	<u>137,866</u>	<u>773,003</u>
Loss before provision for income taxes	(6,045,656)	(7,852,534)	(12,473,283)	(15,278,746)
Provision for income taxes	7,954	7,385	13,167	14,781
Net loss	<u>\$ (6,053,610)</u>	<u>\$ (7,859,919)</u>	<u>\$ (12,486,450)</u>	<u>\$ (15,293,527)</u>
Net loss per share:				
Basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.26)</u>	<u>\$ (0.25)</u>	<u>\$ (0.51)</u>
Weighted average shares outstanding				
Basic and diluted	49,847,872	30,555,012	49,249,430	30,221,168