

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): **May 14, 2024**

**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.

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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 May 14, 2024, disclosing financial information and operating metrics for its fiscal quarter ended March 31, 2024 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) The following exhibit is furnished with this report:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release issued by Reviva Pharmaceuticals Holdings, Inc., dated May 14, 2024.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: May 14, 2024

By: /s/ Narayan Prabhu

Name: Narayan Prabhu

Title: Chief Financial Officer

## Reviva Reports First Quarter 2024 Financial Results and Recent Business Highlights

- Gained alignment with U.S. Food and Drug Administration (FDA) on brilaroxazine clinical trials for New Drug Application (NDA) submission in schizophrenia –
- Registrational RECOVER-2 trial expected to initiate Q2 2024; topline data expected Q3 2025 –
- Topline data from 1-year open-label extension (OLE) trial expected Q4 2024 –

**Cupertino, Calif., May 14, 2024** – 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 first quarter ended March 31, 2024 and summarized recent business highlights.

"This quarter we made strong progress across our late-stage brilaroxazine program in schizophrenia. Importantly, we gained registrational clarity from the FDA on the requirements for an NDA submission which we are on track to complete in the fourth quarter of 2025," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "In 2024, we expect several upcoming catalysts including dosing of the first patient in our registrational RECOVER-2 trial in the second quarter, and topline data from our 1-year OLE trial which will inform on the long-term safety and efficacy of brilaroxazine in the fourth quarter of this year. This is a potentially transformative time for Reviva and we remain focused on our mission to bring brilaroxazine to more patients around the world."

### First Quarter 2024 and Recent Business Highlights

#### Corporate Highlights

- Hosted key opinion leader (KOL) webinar on topline RECOVER-1 Phase 3 data for brilaroxazine and the unmet medical need and current treatment landscape for schizophrenia, featuring presentations by Larry Ereshefsky, PharmD, BCPP, FCCP, of Follow the Molecule and Mark Opler, PhD, MPH of WCG (February 2024)

#### Clinical Program Highlights

- Announced alignment with the U.S. Food and Drug Administration (FDA) on registrational Phase 3 program for brilaroxazine in schizophrenia (April 2024)
    - Acceptance of a 4-week RECOVER-2 study
    - Indication that two positive Phase 3 studies showing efficacy at week 4 that are accompanied by long-term safety data of at least 12 months could be supportive of an NDA submission for the acute treatment of schizophrenia
    - Requirement of a long-term randomized withdrawal study post-approval to support maintenance of effect
  - Presented successful RECOVER-1 Phase 3 clinical trial data for brilaroxazine in schizophrenia at the 2024 Schizophrenia International Research Society (SIRS) Annual Meeting (April 2024)
  - Presented successful RECOVER-1 Phase 3 clinical trial data for brilaroxazine in schizophrenia at the American Society for Clinical Pharmacology & Therapeutics (ASCPT) 2024 Annual Meeting (March 2024)
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## Anticipated Milestones and Events

- Initiation of registrational Phase 3 RECOVER-2 trial evaluating brilaroxazine for the treatment of schizophrenia expected in Q2 2024
- Topline data from 1-year open-label extension (OLE) trial expected Q4 2024
- Topline data from registrational Phase 3 RECOVER-2 trial expected Q3 2025
- Potential NDA submission for brilaroxazine in schizophrenia targeted for Q4 2025
- May initiate Phase 2a studies in bipolar disorder, major depressive disorder, and attention deficit hyperactive disorder in 2024
- Investigational new drug application (IND) submission for liposomal-gel formulation of brilaroxazine in psoriasis expected in 2025
- Pursue partnership opportunities for the development of our pipeline
- Evaluate grant and other non-dilutive financing opportunities for our product candidates from Federal and State Healthcare Agencies and Foundations

## First Quarter 2024 Financial Results

The Company reported a net loss of approximately \$7.4 million, or \$0.25 per share, for the three months ended March 31, 2024, compared to a net loss of approximately \$6.9 million, or \$0.31 per share, for the same period in 2023 (as restated).

As of March 31, 2024, the Company's cash totaled approximately \$12.0 million compared to approximately \$23.4 million as of December 31, 2023.

## About Brilaroxazine

Brilaroxazine is an in-house discovered new chemical entity with potent affinity and selectivity against key serotonin and dopamine receptors implicated in schizophrenia and its comorbid symptoms. Positive topline data from the global Phase 3 RECOVER-1 trial in schizophrenia demonstrated the trial successfully met all primary and secondary endpoints with statistically significant and clinically meaningful reductions across all major symptom domains at week 4 with 50 mg of brilaroxazine vs. placebo with a generally well-tolerated side effect profile comparable to placebo and discontinuation rates lower than placebo. Positive data from a clinical drug-drug interaction (DDI) study investigating the potential effect of CYP3A4 enzyme on brilaroxazine in healthy subjects supports no clinically significant interaction when combined with a CYP3A4 inhibitor. Reviva believes that a full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. Reviva intends to develop brilaroxazine for other neuropsychiatric indications including bipolar disorder, major depressive disorder (MDD) and attention-deficit/hyperactivity disorder (ADHD).

Additionally, brilaroxazine has shown promising nonclinical activity for inflammatory diseases psoriasis, pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF) with mitigation of fibrosis and inflammation in translational animal models. Brilaroxazine has already received Orphan Drug Designation by the U.S. FDA for the treatment of PAH and IPF conditions. To learn more about the clinical and preclinical data available for brilaroxazine, please visit [revivapharma.com/publications](https://www.revivapharma.com/publications).

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**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 1-year open label extension (OLE) trial evaluating the long-term safety and tolerability for brilaroxazine in schizophrenia, the registrational Phase 3 RECOVER-2 trial, 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, clinical and regulatory timelines and expenses, planned or additional studies, planned or intended regulatory submissions including statements about the Company's expectations regarding its planned New Drug Application (NDA) submission in schizophrenia, 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, 2023, 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)**  
**March 31, 2024 and December 31, 2023**

	March 31, 2024	December 31, 2023
<b>Assets</b>		
Cash and cash equivalents	\$ 11,973,647	\$ 23,367,456
Prepaid clinical trial costs	779,602	78,295
Prepaid expenses and other current assets	743,381	254,637
<b>Total Assets</b>	<b>\$ 13,496,630</b>	<b>\$ 23,700,388</b>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
<b>Liabilities</b>		
Short-term debt	\$ 332,000	\$ —
Accounts payable	5,720,455	3,849,108
Accrued clinical expenses	6,845,910	11,966,812
Accrued compensation	1,216,237	958,607
Other accrued liabilities	377,367	400,490
Total current liabilities	14,491,969	17,175,017
Warrant liabilities	350,478	806,655
<b>Total Liabilities</b>	<b>14,842,447</b>	<b>17,981,672</b>
Commitments and contingencies		
<b>Stockholders' Equity (Deficit)</b>		
Common stock, par value of \$0.0001; 115,000,000 shares authorized; 27,918,560 issued and outstanding as of March 31, 2024 and December 31, 2023	2,792	2,792
Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Additional paid-in capital	140,439,247	140,070,172
Accumulated deficit	(141,787,856)	(134,354,248)
Total stockholders' equity (deficit)	(1,345,817)	5,718,716
<b>Total Liabilities and Stockholders' Equity (Deficit)</b>	<b>\$ 13,496,630</b>	<b>\$ 23,700,388</b>

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)  
For the Three Months Ended March 31, 2024 and 2023

	Three Months Ended March 31,	
	2024	2023 (as restated)
Operating expenses		
Research and development	\$ 5,783,865	\$ 5,484,145
General and administrative	2,138,241	1,500,554
Total operating expenses	7,922,106	6,984,699
Loss from operations	(7,922,106)	(6,984,699)
Other income (expense)		
Gain on remeasurement of warrant liabilities	456,177	11,126
Interest expense	(3,487)	(7,655)
Interest income	173,098	147,011
Other expense	(129,894)	(14,494)
Total other income, net	495,894	135,988
Loss before provision for income taxes	(7,426,212)	(6,848,711)
Provision for income taxes	7,396	2,978
<b>Net loss</b>	<b>\$ (7,433,608)</b>	<b>\$ (6,851,689)</b>
<b>Net loss per share:</b>		
<b>Basic and diluted</b>	<b>\$ (0.25)</b>	<b>\$ (0.31)</b>
<b>Weighted average shares outstanding</b>		
<b>Basic and diluted</b>	<b>29,887,325</b>	<b>21,833,598</b>