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

- Topline data from 1-year open-label extension (OLE) trial expected Q4 2024 -
- Registrational RECOVER-2 trial in schizophrenia expected to initiate Q3 2024; topline data expected Q4 2025 -
- European patent granted covering brilaroxazine use for treating pulmonary hypertension
   (PH) and pulmonary arterial hypertension (PAH) in any patients -
- U.S. patent granted covering use of brilaroxazine for the treatment of idiopathic pulmonary fibrosis (IPF) -

CUPERTINO, Calif., Aug. 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 second quarter ended June 30, 2024 and summarized recent business highlights.

"Our late-stage brilaroxazine program continues to advance with topline data from our 1-year open-label extension trial evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia expected in the fourth quarter of the year," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "We also further expanded our intellectual property for brilaroxazine to cover additional large markets for PH and IPF which are similarly driven by the underlying disruption in serotonin signaling. We believe brilaroxazine continues to show a differentiated safety and efficacy profile in the over 800 patients with schizophrenia treated to date in our trials, and we are highly encouraged by its broad therapeutic potential across indications."

#### **Second Quarter 2024 and Recent Business Highlights**

### **Corporate Highlights**

- United States (U.S.) Patent 12053477 has been granted by the U.S. Patent and Trademark Office (USPTO) covering use of brilaroxazine for the treatment of idiopathic pulmonary fibrosis (IPF), adding to its existing patent protection in key markets around the world including Japan. Brilaroxazine has received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of IPF (August 2024).
- European Patent (EP3244896) granted by the European Patent Office (EPO) covering use of brilaroxazine for the treatment of pulmonary hypertension (PH), adding to its existing patent protection in key markets around the world including the United States,

China and Japan. The European patent covers brilaroxazine use for treating pulmonary hypertension (PH) and pulmonary arterial hypertension (PAH) in any patients and treating PH in patients with COPD or SCD. Brilaroxazine has received an Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for the treatment of PAH (July 2024).

## **Clinical Program Highlights**

- Provided an enrollment update to the ongoing 1-year open-label extension (OLE) study evaluating the long-term safety and tolerability of brilaroxazine in patients with schizophrenia (August 2024).
  - Trial progressing as expected in the USA, Europe (Bulgaria) and Asia (India)
  - 424 patients enrolled in the study; 230 patients currently on treatment in the study
  - 65 patients have completed 12 months of treatment
  - 53 patients who completed 9 months treatment currently in the study
  - About 200 patients completed 6 months of treatment
  - 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
  - Reviva is on track to complete the 12 months long-term safety study in Q4 2024
- Announced alignment with 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 Phase 3 clinical trial data for brilaroxazine in schizophrenia at the 2024 Schizophrenia International Research Society (SIRS) Annual Meeting (April 2024)

### **Anticipated Milestones and Events**

- Initiation of registrational Phase 3 RECOVER-2 trial evaluating brilaroxazine for the treatment of schizophrenia expected in Q3 2024
- Topline data from 1-year open-label extension (OLE) trial expected Q4 2024
- Topline data from registrational Phase 3 RECOVER-2 trial expected Q4 2025
- Potential NDA submission for brilaroxazine in schizophrenia targeted for Q1 2026

- 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

## **Second Quarter 2024 Financial Results**

The Company reported a net loss of approximately \$7.9 million, or \$0.26 per share, for the three months ended June 30, 2024, compared to a net loss of approximately \$11.7 million, or \$0.52 per share, for the same period in 2023 (as restated).

The Company reported a net loss of approximately \$15.3 million, or \$0.51 per share, for the six months ended June 30, 2024, compared to a net loss of approximately \$18.6 million, or \$0.84 per share, for the same period in 2023 (as restated).

As of June 30, 2024, the Company's cash totaled approximately \$6.2 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 the pathobiology of several conditions including schizophrenia, psoriasis and interstitial lung diseases like pulmonary hypertension, pulmonary arterial hypertension (PAH) and idiopathic pulmonary fibrosis (IPF).

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 including reduction in key proinflammatory cytokines implicated in the pathobiology of schizophrenia and comorbid inflammatory conditions 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.

#### **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 and clinical trial plans, 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 forwardlooking 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) June 30, 2024 and December 31, 2023

	June 30,	December 31,
	2024	2023
Assets		
		23,367,45
Cash and cash equivalents	\$6,178,180	\$ 6
Prepaid clinical trial costs	528,947	78,295
Prepaid expenses and other current assets	525,826	254,637
		23,700,38
Total current assets	7,232,953	8
Non-current prepaid clinical trial costs	819,721	-
		23,700,38
Total Assets	\$8,052,674	\$ 8
Liabilities and Stockholders' Equity (Deficit)		<u> </u>
Liabilities		
Short-term debt	\$ 207,500	\$ -
Accounts payable	4,693,360	3,849,108
		11,966,81
Accrued clinical expenses	7,301,782	2
Accrued compensation	1,295,978	958,607
Other accrued liabilities	445,371	400,490
	13,943,99	17,175,01
Total current liabilities	1	7
Warrant liabilities	150,205	806,655

Total Liabilities         6         2           Commitments and contingencies         Stockholders' Equity (Deficit)           Common stock, par value of \$0.0001; 115,000,000 shares authorized; 29,817,294 and 27,918,560 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively         2,982         2,792           Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023         -		14,094,19	17,981,67
Stockholders' Equity (Deficit)         Common stock, par value of \$0.0001; 115,000,000 shares authorized; 29,817,294 and 27,918,560 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively       2,982       2,792         Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023       -       -       -         Additional paid-in capital       71       72       (149,603,2)       140,070,1       72         Accumulated deficit       775)       248)       (6,041,52)       248)         Total stockholders' equity (deficit)       2)       5,718,716       23,700,38	Total Liabilities	6	2
Common stock, par value of \$0.0001; 115,000,000 shares authorized; 29,817,294 and 27,918,560 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively 2,982 2,792  Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023 143,603,2 140,070,1  Additional paid-in capital 71 72  Accumulated deficit 775 (194,647, (134,354, 475) 248)  Total stockholders' equity (deficit) 2) 5,718,716 23,700,38	Commitments and contingencies		
29,817,294 and 27,918,560 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively 2,982 2,792  Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of June 30, 2024 and December 31, 2023	Stockholders' Equity (Deficit)		
2023 - 143,603,2 140,070,1 Additional paid-in capital 71 72  Accumulated deficit 775) 248)  Total stockholders' equity (deficit) 2) 5,718,716 23,700,38	29,817,294 and 27,918,560 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively Preferred Stock, par value of \$0.0001; 10,000,000 shares authorized; 0		2,792
Additional paid-in capital 71 72  (149,647, (134,354, 775) 248)  Accumulated deficit 775) 248)  Total stockholders' equity (deficit) 2) 5,718,716  23,700,38	•	_	_
Accumulated deficit 775) 248)  (6,041,52  Total stockholders' equity (deficit) 2) 5,718,716  23,700,38	Additional paid-in capital	·	
Total stockholders' equity (deficit)  2) 5,718,716  23,700,38	Accumulated deficit	. , ,	
¢ 0 052 674 ¢ 0	Total stockholders' equity (deficit)	. , , ,	5,718,716
	Total Liabilities and Stockholders' Equity (Deficit)	\$8,052,674	

# REVIVA PHARMACEUTICALS HOLDINGS, INC. CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED) For the Three and Six Months Ended June 30, 2024 and 2023

	•	Three Months Ended June 30,			Six Months Ended June 30,		
		2024		2023	2024		2023
				(as			(as
Operating expenses			ı	restated)			restated)
					11,368,21		13,740,48
Research and development		5,584,347				•	1
General and administrative		2,545,296	3	3,079,301	4,683,537	•	4,579,855
			1	11,335,63	16,051,74		18,320,33
Total operating expenses		8,129,643		7	9		6
		(8,129,64		(11,335,6	(16,051,7		(18,320,3
Loss from operations		3)		37)	49)		36)
Other income (expense)							
Gain (loss) on remeasurement of warrant							
liabilities		200,273		(456,177)	656,450		(445,051)
Interest expense		(5,153)		(12,759)	(8,640)		(20,414)
Interest income		87,610		103,080	260,708		250,091
Other expense, net		(5,621)		(19)	(135,515)		(14,513)
Total other income (expense), net		277,109		(365,875)	773,003		(229,887)
		(7,852,53		(11,701,5	(15,278,7		(18,550,2
Loss before provision for income taxes		4)		12)	46)		23)
Provision for income taxes		7,385		6,436	14,781		9,414
		(7,859,91		(11,707,9	(15,293,5		(18,559,6
Net loss	\$	9)	\$	48)	\$ 27)	\$	37)
Net loss per share:			П				
Basic and diluted	\$	(0.26)	\$	(0.52)	\$ (0.51)	\$	(0.84)

## Weighted average shares outstanding

