Reviva Reports Third Quarter 2024 Financial Results and Recent Business Highlights

– 108 patients have completed 1-year of treatment in 1-year open-label extension (OLE) trial –

– Vocal biomarker speech latency data from RECOVER trial reinforce brilaroxazine's improvement on negative symptoms and other key symptom domains of schizophrenia –

– Topline data from OLE trial expected in December 2024 –

CUPERTINO, Calif., Nov. 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 third quarter ended September 30, 2024 and summarized recent business highlights.

"We continue to advance our late-stage brilaroxazine program with initial focus in schizophrenia and expansion potential across indications driven by underlying disruption in serotonin signaling," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "Our global 1-year OLE trial is progressing well, and we have over 100 patients who have completed one year of treatment which is a requirement for New Drug Application (NDA) submission. Importantly, we expect topline data from the OLE trial in December 2024. In addition to long-term safety, tolerability and efficacy, the full data analysis of the OLE trial expected in the first quarter of 2025 will also include vocal and blood biomarker data designed to support the strong efficacy of brilaroxazine for negative symptoms and other key symptom domains of schizophrenia. We remain highly encouraged by the differentiated potential of once-daily brilaroxazine to address major unmet needs for patients with schizophrenia and are targeting a potential NDA submission for brilaroxazine in the second quarter of 2026."

Third Quarter 2024 and Recent Business Highlights

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 (November 2024).
    - Global trial progressing well
    - 108 patients have completed 1-year (12-month) of treatment
    - Over 250 patients have completed 6-months of treatment
    - Blood and digital biomarkers designed to independently support 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
    - 12 months long-term safety study expected to complete in Q1 2025

- Presented vocal biomarker data from Phase 3 RECOVER trial of brilaroxazine in schizophrenia during a virtual key opinion leader event hosted by the Company featuring Brian Kirkpatrick, MD, MSPH (Professor, Psychiatric Research Institute, University of Arkansas for Medical Sciences, Arkansas) and Mark Opler, PhD, MPH (Chief Research Officer at WCG Inc., Executive Director of the PANSS Institute, New York) (September 2024).
    - Speech latency is an emerging objective vocal biomarker that can help validate scale-based assessments completed by human raters
    - Brilaroxazine demonstrated a strong efficacy for negative symptoms and other key symptoms of schizophrenia such as total and positive symptoms, disorganization, and social functioning in the pivotal phase 3 RECOVER trial in schizophrenia
    - Statistically significant results of the vocal biomarker speech latency data analysis from the RECOVER trial further support the strong efficacy of brilaroxazine for negative symptoms and other key symptom domains of schizophrenia

Corporate Highlights

- Positive speech latency data for brilaroxazine in schizophrenia from the Phase 3 RECOVER trial presented as a poster presentation at the Central Nervous System (CNS) Summit 2024 on Tuesday, November 12th in Boston, Massachusetts

Anticipated Milestones and Events

- Topline data from 1-year OLE trial expected in December 2024
- Full data analysis of the OLE trial including long-term safety, tolerability and efficacy, as well as vocal and blood biomarker data expected in Q1 2025
- Initiation of registrational Phase 3 RECOVER-2 trial evaluating brilaroxazine for the treatment of schizophrenia expected in Q1 2025, subject to receipt of additional financing
- Potential NDA submission for brilaroxazine in schizophrenia targeted for Q2 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

Third Quarter 2024 Financial Results

The Company reported a net loss of approximately $8.4 million, or $0.25 per share, for the three months ended September 30, 2024, compared to a net loss of approximately $11.3 million, or $0.48 per share, for the same period in 2023 (as restated).

The Company reported a net loss of approximately $23.7 million, or $0.75 per share, for the nine months ended September 30, 2024, compared to a net loss of approximately $29.9 million, or $1.32 per share, for the same period in 2023 (as restated).

As of September 30, 2024, the Company's cash totaled approximately $5.6 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 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)
September 30, 2024 and December 31, 2023

	September 30, 2024	December 31, 2023
Assets		
Cash and cash equivalents	$5,558,817	$ 23,367,456
Prepaid clinical trial costs	925,526	78,295
Prepaid expenses and other current assets	325,808	254,637
Total current assets	6,810,151	23,700,388
Non-current prepaid clinical trial costs	819,721	–
Total Assets	$7,629,872	$ 23,700,388
Liabilities and Stockholders' Equity (Deficit)		
Liabilities		
Short-term debt	$ 83,000	$ –
Accounts payable	8,777,579	3,849,108
Accrued clinical expenses	7,362,666	11,966,812
Accrued compensation	881,830	958,607
Other accrued liabilities	428,801	400,490
Total current liabilities	17,533,876	17,175,017
Warrant liabilities	77,884	806,655
Total Liabilities	17,611,760	17,981,672
Commitments and contingencies (Note 6)		
Stockholders' Equity (Deficit)		
Common stock, par value of $0.0001; 115,000,000 shares authorized; 33,441,199 and 27,918,560 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	3,344	2,792
Preferred Stock, par value of $0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	–	–

Additional paid-in capital	148,028,341	140,070,172
Accumulated deficit	(158,013,573)	(134,354,248)
Total stockholders' equity (deficit)	(9,981,888)	5,718,716
Total Liabilities and Stockholders' Equity (Deficit)	$7,629,872	$ 23,700,388

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses		(as restated)		(as restated)
Research and development	$ 6,858,285	$ 9,572,180	$ 18,226,497	$ 23,312,661
General and administrative	1,604,249	1,991,774	6,287,786	6,571,629
Total operating expenses	8,462,534	11,563,954	24,514,283	29,884,290
Loss from operations	(8,462,534)	(11,563,954)	(24,514,283)	(29,884,290)
Other income (expense)				
Gain (loss) on remeasurement of warrant liabilities	72,321	139,079	728,771	(305,972)
Interest expense	(5,146)	(5,901)	(13,786)	(20,414)
Interest income	53,248	91,763	313,956	341,854
Other income (expense), net	(23,687)	5,194	(159,202)	(15,220)
Total other income, net	96,736	230,135	869,739	248
Loss before provision for income taxes	(8,365,798)	(11,333,819)	(23,644,544)	(29,884,042)
Provision for income taxes	–	12,117	14,781	21,531
Net loss	$ (8,365,798)	$ (11,345,936)	$ (23,659,325)	$ (29,905,573)
Net loss per share:				
Basic and diluted	$ (0.25)	$ (0.48)	$ (0.75)	$ (1.32)
Weighted average shares outstanding				
Basic and diluted	33,804,693	23,637,367	31,424,395	22,655,737