

## **Reviva Reports Second Quarter 2023 Financial Results and Recent Business Highlights**

- *Topline data for global pivotal Phase 3 RECOVER trial for brilaroxazine in schizophrenia expected in October 2023 -*
- *Completion of 1-year open-label extension clinical trial for brilaroxazine in schizophrenia expected in Q3 2024 -*

CUPERTINO, Calif., Aug. 14, 2023 — Reviva Pharmaceuticals Holdings, Inc. (NASDAQ: RVPH) (“Reviva” or the “Company”), 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, today reported financial results for the second quarter ended June 30, 2023 and summarized recent business highlights.

“We continued the momentum this quarter by further bolstering foundational support for the broad application of our new chemical entity brilaroxazine, highlighting a differentiated clinical pharmacology and safety profile at this year’s ASPET annual meeting, and the multifaceted activity and potential to treat inflammatory diseases like psoriasis at the International Societies for Investigative Dermatology (ISID) Meeting, and idiopathic pulmonary fibrosis (IPF) at the annual American Thoracic Society (ATS) international conference,” said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. “Brilaroxazine continues to demonstrate a well-tolerated safety profile with a unique potential to improve multiple symptom domains and neuroinflammation in schizophrenia. This upcoming quarter will be an exciting time for Reviva with topline data from our pivotal global RECOVER Phase 3 trial expected in October 2023, potentially leading to significant inflection points in the clinical development of brilaroxazine for schizophrenia and expansion opportunities across other conditions driven by dysfunctional serotonin-dopamine signalling.”

### **Second Quarter 2023 Highlights and Recent Business Highlights**

#### **Corporate Highlights**

- Joined the Russell Microcap® Index with automatic inclusion in the appropriate growth and value style indexes (June 2023)
- Announced positive preclinical data for brilaroxazine in idiopathic pulmonary fibrosis (IPF) at the 2023 American Thoracic Society (ATS) International Conference and publication in *Medical Research Archives* (May 2023)
- Presented promising clinical pharmacology and safety data for brilaroxazine at the American Society for Pharmacology and Experimental Therapeutics (ASPET) 2023 annual meeting (May 2023)
- Presented on the liposomal-gel formulation of brilaroxazine and potential in psoriasis at

the International Societies for Investigative Dermatology (ISID) Meeting (May 2023)

- Hosted key opinion leader webinar on brilaroxazine for the treatment of schizophrenia, featuring a presentation by Larry Ereshefsky, PharmD (Follow the Molecule LLC) (May 2023)
- Presented foundational preclinical data on brilaroxazine in schizophrenia at the 78th Annual Scientific Convention of the Society of Biological Psychiatry (SOBP) and publication in *Medical Research Archives* (May 2023)

### **Clinical Program Highlights**

- Enrollment near completion for approximately 400 patients across multiple sites in the United States, Europe, and Asia for pivotal Phase 3 RECOVER trial
- Over 50% of patients currently enrolled in the 1-year open-label extension (OLE) study for brilaroxazine in schizophrenia.

### **Anticipated Milestones and Events**

- Topline data for pivotal Phase 3 RECOVER trial evaluating brilaroxazine for the treatment of schizophrenia expected in October 2023
- May initiate Phase 2a studies in bipolar disorder, major depressive disorder, and attention deficit hyperactive disorder in second half 2023, subject to the receipt of additional financing
- Completion of the required 100 patients treated with brilaroxazine for 1-year in the OLE study expected in Q3 2024
- Submit investigational new drug application (IND) for liposomal-gel formulation of brilaroxazine in psoriasis expected in 2024
- 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

### **Second Quarter 2023 Financial Results**

The Company reported a net loss of approximately \$12.4 million, or (\$0.55) per share, for the three months ended June 30, 2023, compared to a net loss of approximately \$5.3 million, or (\$0.29) per share, for the same period in 2022. The increase in net loss was primarily attributable to an increase in research and development expenses of approximately \$4.5 million and an increase in general and administrative expenses of approximately \$2.1 million for the three months ended June 30, 2023.

As of June 30, 2023, the Company's cash totaled approximately \$11.2 million compared to approximately \$18.5 million as of December 31, 2022.

Reviva believes that based on the current operating plan and financial resources, the

Company's cash as of June 30, 2023 will be sufficient to fund current operating plans well into the fourth quarter of 2023.

### **First Six Months Fiscal Year 2023 Financial Results**

The Company reported a net loss of approximately \$19.0 million, or (\$0.86) per share, for the six months ended June 30, 2023, compared to a net loss of approximately \$12.7 million, or (\$0.69) per share, for the same period in 2022. The increase in net loss was primarily attributable to an increase in research and development expenses of approximately \$3.9 million and an increase in general and administrative expenses of approximately \$2 million for the six months ended June 30, 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. In a multinational, multicenter, double-blind Phase 2 study in 234 patients with acute schizophrenia or schizoaffective disorder, brilaroxazine met its primary endpoint, reducing Positive and Negative Syndrome Scale (PANSS) total score and demonstrating statistically significant improvement of overall drug treatment outcomes using Clinical Global Impression (CGI) scale and for secondary endpoints evaluating social functioning, and positive and negative symptoms, and directional improvements for depression and cognition. In this completed Phase 2 study, brilaroxazine met all safety endpoints with no weight gain, no increase in blood sugar and lipids, and no cardiac or endocrine adverse effects compared to 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. A full battery of regulatory compliant toxicology and safety pharmacology studies has been completed for brilaroxazine. The U.S. Food and Drug Administration (FDA) has agreed to consider a potential superior safety label claim if there is a positive outcome on a relevant endpoint in a pivotal Phase 3 study in patients with schizophrenia. 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 efficacy 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).

## **About Reviva**

Reviva is a late-stage pharmaceutical 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, inflammatory and cardiometabolic diseases. Reviva's pipeline currently includes two drug candidates, RP5063 (brilaroxazine) and RP1208. Both are new chemical entities discovered in-house. Reviva has been granted composition of matter patents for both RP5063 and RP1208 in the United States (U.S.), 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 Phase 3 RECOVER study and timing of topline data, the Company's open-label extension clinical trial for brilaroxazine in schizophrenia, 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, market opportunity, ability to raise sufficient funding, competitive position, possible or assumed future results of operations, business strategies, potential 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, 2022, 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.

**Corporate Contact:**

Reviva Pharmaceuticals Holdings, Inc.  
Laxminarayan Bhat, PhD  
www.revivapharma.com

**Investor Relations Contact:**

LifeSci Advisors, LLC  
Bruce Mackle  
bmackle@lifesciadvisors.com

**REVIVA PHARMACEUTICALS HOLDINGS, INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**  
**June 30, 2023 and December 31, 2022**

	<b>June 30, 2023</b>	<b>December 31, 2022</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 11,151,582	\$ 18,519,856
Prepaid expenses and other current assets	690,440	403,819
<b>Total Assets</b>	<b>\$ 11,842,022</b>	<b>\$ 18,923,675</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Liabilities</b>		
Short-term debt	\$ 222,500	\$ -
Accounts payable	2,648,287	3,520,271
Accrued expenses and other current liabilities	6,337,558	2,519,569
Total current liabilities	9,208,345	6,039,840
Warrant liabilities	1,012,490	567,439
<b>Total Liabilities</b>	<b>10,220,835</b>	<b>6,607,279</b>
Commitments and contingencies (Note 8)		
<b>Stockholders' equity</b>		
Common stock, par value of \$0.0001; 115,000,000 shares authorized; 22,650,266 and 20,447,371 shares issued and outstanding as of June 30, 2023, and December 31, 2022, respectively	2,265	2,045
Additional paid-in capital	111,835,588	103,485,612
Accumulated deficit	(110,216,666)	(91,171,261)
Total stockholders' equity	<b>1,621,187</b>	<b>12,316,396</b>
<b>Total Liabilities and Stockholders' Equity</b>	<b>\$ 11,842,022</b>	<b>\$ 18,923,675</b>

**REVIVA PHARMACEUTICALS HOLDINGS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**  
**For the Three and Six Months Ended June 30, 2023 and 2022**

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses				
Research and development	\$ 8,991,250	\$ 4,514,389	\$ 14,226,249	\$ 10,344,407
General and administrative	3,079,301	1,005,099	4,579,855	2,625,238
	12,070,55		18,806,10	12,969,64
Total operating expenses	1	5,519,488	4	5
	(12,070,55		(18,806,10	(12,969,64
Loss from operations	1)	(5,519,488)	4)	5)
Other (expense) income				
(Loss) gain on remeasurement of warrant liabilities	(456,177)	178,021	(445,051)	267,031
Interest expense	(12,759)	-	(20,414)	-
Interest income	103,080	13,825	250,091	15,560
Other expense	(19)	(6,141)	(14,513)	(8,108)
Total other (expense) income, net	(365,875)	185,705	(229,887)	274,483
	(12,436,42		(19,035,99	(12,695,16
Loss before provision for income taxes	6)	(5,333,783)	1)	2)
Provision for income taxes	6,436	6,921	9,414	10,550
	(12,442,86		(19,045,40	(12,705,71
<b>Net loss</b>	\$ 2)	\$ (5,340,704)	\$ 5)	\$ 2)
<b>Net loss per share:</b>				
<b>Basic and diluted</b>	\$ (0.55)	\$ (0.29)	\$ (0.86)	\$ (0.69)
<b>Weighted average shares outstanding</b>				
	22,434,78	18,466,58	22,135,85	18,466,58
<b>Basic and diluted</b>	1	6	0	6

