Reviva Reports Third Quarter 2025 Financial Results and Recent Business Highlights

- Pre-NDA meeting with FDA to discuss brilaroxazine's path to approval for schizophrenia planned in Q4 2025 -

- Potential NDA submission for schizophrenia indication targeted for Q2 2026 -

- European patent granted covering use of brilaroxazine for the treatment of pulmonary fibrosis adds to existing patent protection in key global markets -

CUPERTINO, Calif., Nov. 13, 2025 (GLOBE NEWSWIRE) -- 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, 2025 and summarized recent business highlights.

"With the comprehensive clinical and non-clinical data package in hand, we believe brilaroxazine is strongly positioned to meet New Drug Application (NDA) filing requirements and advance toward potential registration for schizophrenia," said Laxminarayan Bhat, Ph.D., Founder, President, and CEO of Reviva. "The consistent body of evidence for brilaroxazine, from early clinical studies through long-term extension studies, continues to demonstrate broad-spectrum, durable efficacy, a favorable safety profile, and strong long-term adherence with once-daily dosing. We are preparing for a pre-NDA meeting with the Food and Drug Administration (FDA) in the fourth quarter of the year and continue to target a potential NDA submission in the second quarter of 2026. We believe brilaroxazine's differentiated clinical profile has the potential to redefine treatment expectations in schizophrenia and significantly improve patient outcomes worldwide."

Clinical Program and Business Highlights

- European Patent (EP3749324) granted by the European Patent Office (EPO) covering use of brilaroxazine for the treatment of pulmonary fibrosis, including idiopathic pulmonary fibrosis (IPF), adding to Reviva's existing patent protection in key markets around the world including the United States, China and Japan. Brilaroxazine previously received Orphan Drug Designation from the U.S. FDA for the treatment of IPF in July 2024.

- 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 (N=446) in June 2025 and additional analyses in October 2025. A summary of the OLE results is provided here:

    - Once daily brilaroxazine (pooled 15, 30, and 50 mg, N=159) in patient population completed one year treatment, 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), negative symptoms Marder factor (-4.4), general psychopathology (-8.7), personal & social performance (11.3) and CGI-S (-0.8, a 1 point improvement in 78% of patients)
    - No clinically meaningful changes in movement disorder scales used for evaluating motor side effects such as akathisia and extrapyramidal symptoms.
    - Benign weight gain (~1.5 kg) compared to baseline over 52 weeks (1 year treatment). The weight gain is not dose-dependent and possibly related to lifestyle or diet
    - Favorable and consistent improvement in lipid profile, and blood sugar levels were comparable to baseline over 52 weeks (1 year) across all 3 dose groups

- Not associated with hormonal imbalance and sexual side effects. Elevated prolactin levels reported at the beginning of the study were significantly reduced to normal or near normal in all three dose groups. Improvement in thyroid hormone levels and sexual function reported
- No incidence of clinically significant cardiac or gastrointestinal side effects. No incidence of drug induced liver injury (DILI)
- Generally well tolerated with a discontinuation rate of 35% after 1-year for pooled doses of brilaroxazine

- Continuing efforts have 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.

- Completed public equity offering raising gross proceeds of $9.0 million, before deducting placement agent fees and other offering expenses.

- Presented a poster presentation on negative symptom data for brilaroxazine from the Phase 3 RECOVER double-blind trial in patients with acute exacerbation of schizophrenia, and from the long-term open-label extension trial in clinically stable schizophrenia patients at the Central Nervous System (CNS) Summit in Boston, MA, November 2-5, 2025

- Scheduled to present a late-breaking poster presentation on the anti-inflammatory biomarker data for brilaroxazine from the Phase 3 RECOVER double-blind trial in patients with acute exacerbation of schizophrenia, and from the long-term open-label extension trial in clinically stable schizophrenia patients at the Society for Neuroscience Annual Meeting in San Diego, CA, November 15-19, 2025

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
- Investigational new drug application (IND) submission for liposomal-gel formulation of brilaroxazine in psoriasis expected by H2-2026
- Pursuing partnership opportunities for the development of our pipeline

Financial Results for September 30, 2025

- The Company reported a net loss of approximately $4.0 million, or $0.06 per share, for the three months ended September 30, 2025, compared to a net loss of approximately $8.4 million, or $0.25 per share, for the three months ended September 30, 2024.

- As of September 30, 2025, the Company's cash and cash equivalents totaled approximately $13.2 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)

	September 30, 2025	December 31, 2024
Assets		
Cash and cash equivalents	$13,183,259	$13,476,331
Prepaid clinical trial costs	81,742	540,601
Prepaid expenses and other current assets	247,927	666,435
Total current assets	13,512,928	14,683,367
Non-current prepaid clinical trial costs	819,721	819,721
Total Assets	$14,332,649	$15,503,088
Liabilities and Stockholders' Equity		
Liabilities		
Short-term debt	$-	$458,154
Accounts payable	5,431,806	6,283,430
Accrued clinical expenses	2,891,175	6,723,719
Accrued compensation	784,956	635,587
Other accrued liabilities	630,471	500,616
Total current liabilities	9,738,408	14,601,506
Warrant liabilities	44,506	89,010
Total Liabilities	9,782,914	14,690,516
Commitments and contingencies		
Stockholders' Equity		
Common stock, par value of $0.0001; 315,000,000 shares authorized; 96,337,119 and 46,579,199 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	9,618	4,658
Preferred Stock, par value of $0.0001; 10,000,000 shares authorized; 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024	-	-
Additional paid-in capital	185,310,390	165,080,964
Accumulated deficit	(180,770,273)	(164,273,050)
Total stockholders' equity	4,549,735	812,572
Total Liabilities and Stockholders' Equity	$14,332,649	$15,503,088

REVIVA PHARMACEUTICALS HOLDINGS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses				
Research and development	$2,131,444	$6,858,285	$9,969,736	$18,226,497
General and administrative	1,898,397	1,604,249	6,671,254	6,287,786
Total operating expenses	4,029,841	8,462,534	16,640,990	24,514,283
Loss from operations	(4,029,841)	(8,462,534)	(16,640,990)	(24,514,283)
Other income (expense)				
(Loss) gain on remeasurement of warrant liabilities	(27,816)	72,321	44,504	728,771
Interest expense	(2,605)	(5,146)	(19,022)	(13,786)
Interest income	59,103	53,248	168,061	313,956
Other expense, net	(6,774)	(23,687)	(33,769)	(159,202)
Total other income, net	21,908	96,736	159,774	869,739
Loss before provision for income taxes	(4,007,933)	(8,365,798)	(16,481,216)	(23,644,544)
Provision for income taxes	2,840	-	16,007	14,781
Net loss	$(4,010,773)	$(8,365,798)	$(16,497,223)	$(23,659,325)
Net loss per share:				
Basic and diluted	$(0.06)	$(0.25)	$(0.29)	$(0.75)
Weighted average shares outstanding				
Basic and diluted	72,685,740	33,804,693	57,147,381	31,424,395

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