Rallybio Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

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— Key Data Readouts from Sentinel Participant in RLYB212 Phase 2 Clinical Trial Expected in 2Q 2025 and 3Q 2025 —

— Initiation of RLYB116 Confirmatory PK/PD Study Expected in 2Q 2025, with Data Anticipated in 2H 2025 —

—$65.5 Million in Cash, Cash Equivalents, and Marketable Securities as of December 31, 2024 Provides Runway into 2H 2026 —

NEW HAVEN, Conn.--(BUSINESS WIRE)--Mar. 13, 2025-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided an update on recent company developments.

“We are pleased with our strong execution in 2024, and look forward to reporting on our planned milestones in 2025," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Dosing in our RLYB212 Phase 2 trial is underway, our differentiated C5 inhibitor, RLYB116, is on track to enter a confirmatory pharmacokinetic/pharmacodynamic study in the second quarter, and our potentially best-in-class ENPP1 inhibitor for patients with hypophosphatasia, REV102, is advancing toward Phase 1 in 2026. Through exceptional execution of these programs and continued financial discipline, we are laser focused on driving value for Rallybio in 2025 and positioning the Company for sustained growth and success in the future."

Recent Business Highlights and Upcoming Milestones:

RLYB212 Program

- In February 2025, Rallybio announced that the sentinel participant was dosed in the Phase 2 trial investigating RLYB212 in pregnant women at higher risk for HPA-1a alloimmunization and fetal and neonatal alloimmune thrombocytopenia (FNAIT). Pharmacokinetic (PK) and safety data from the second trimester are expected in the second quarter of 2025, with PK and safety data at the time of delivery expected in the third quarter of 2025. The Company received regulatory approval to begin the Phase 2 trial in October 2024 and initiated screening in November 2024.

- More than 14,300 pregnant women were screened in Rallybio’s FNAIT natural history study as of January 31, 2025, at which time screening was concluded at sites in the United States and Canada. Natural history data will continue to be collected in a sub-study of the Phase 2 trial, where participants at higher risk for HPA-1a alloimmunization and FNAIT who do not receive RLYB212 are eligible to enroll.

- Rallybio expects to present interim data from the FNAIT natural history study in mid-2025, including data evaluating the frequency of FNAIT risk across racial and ethnic populations.

RLYB116 Program

- In December 2024, Rallybio presented biomarker characterization analyses indicating that RLYB116 led to a meaningfully greater degree of complement inhibition in the Phase 1 multiple ascending dose (MAD) study than initially reported and as a result, may be effective in treating a broad range of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria (PNH), generalized myasthenia gravis (gMG), and antiphospholipid syndrome (APS).

- Rallybio plans to initiate a confirmatory clinical pharmacokinetic/pharmacodynamic (PK/PD) study in the second quarter of 2025, with data readouts from Cohorts 1 and 2 expected in the third and fourth quarter of 2025, respectively.

REV102 Program

- Rallybio advanced REV102, an ENPP1 inhibitor for the treatment of patients with hypophosphatasia (HPP), which is being developed through a joint venture with Recursion Pharmaceuticals.

- Investigational new drug application (IND)-enabling studies are underway to support the initiation of a Phase 1 study in 2026.

- Presentation of data evaluating REV102 in a preclinical model of later-onset HPP is expected in the second half of 2025.

RLYB332 Program

- In December 2024, Rallybio presented preclinical data for RLYB332 at the American Society for Hematology (ASH) annual meeting, which demonstrated that single intravenous injections of RLYB332 to humanized FcRn mice had rapid and sustained effects on PD parameters, including serum iron, unsaturated iron binding capacity (UIBC), and transferrin saturation (TSAT), with greater impact than those produced by comparator molecules.

- The favorable PD data relative to comparator molecules support RLYB332 as a long-acting, potentially best-in-class therapy for the treatment of diseases of iron overload.

Fourth Quarter and Full Year 2024 Financial Results

- **Revenue:** Revenue was $38 thousand for the fourth quarter of 2024 and $0.6 million for the year ended December 31, 2024, compared to no revenue in the same periods in 2023. The increase in revenue for both the fourth quarter of 2024 and the year ended December 31, 2024 was related to Rallybio's entrance into the collaboration agreement with Johnson & Johnson in the second quarter of 2024 and the recognition of revenue related to the collaboration's performance obligations.

- **Research & Development (R&D) Expenses:** R&D expenses were $7.4 million for the fourth quarter of 2024, compared to $15.9 million for the same period in 2023. R&D expenses were $41.5 million for the year ended December 31, 2024 compared to $53.5 million for the year ended December 31, 2023. The decrease in R&D expenses for both the fourth quarter of 2024 and the year ended December 31, 2024 was primarily due to a decrease in development costs related to RLYB212, RLYB116 and other program candidates, in addition to a decrease in payroll and personnel-related costs, largely related to the workforce reduction.

- **General & Administrative (G&A) Expenses:** G&A expenses were $4.3 million for the fourth quarter of 2024, compared to $5.2 million for the same period in 2023. G&A expenses were $19.6 million for the year ended December 31, 2024, compared to $25.4 million for the year ended December 31, 2023. The decrease in G&A expenses for both the fourth quarter of 2024 and the year ended December 31, 2024 was primarily due to a decrease in other general and administrative expenses including consulting fees, director and officer insurance premiums and professional fees, in addition to lower payroll and personnel-related costs, largely related to the workforce reduction and lower ongoing headcount in 2024 as compared to 2023.

- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net loss of $11.0 million, or $0.25 per common share, for the fourth quarter of 2024 compared to a net loss of $20.2 million, or $0.50 per common share, for the same period in 2023. A net loss of $57.8 million, or $1.33 per common share, was reported for the year ended December 31, 2024 compared to a net loss of $74.6 million, or $1.84 per common share, for the year ended December 31, 2023.

- **Cash Position:** As of December 31, 2024, cash, cash equivalents, and marketable securities were $65.5 million. Rallybio expects these funds will be sufficient to support operations into the second half of 2026.

About Rallybio

Rallybio (NASDAQ: RLYB) is a clinical-stage biotechnology company with a mission to develop and commercialize life-transforming therapies for patients with severe and rare diseases. Rallybio has built a broad pipeline of promising product candidates aimed at addressing diseases with unmet medical need in areas of maternal fetal health, complement dysregulation, hematology, and metabolic disorders. The Company has two clinical stage programs: RLYB212, an anti-HPA-1a antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT) and RLYB116, a C5 inhibitor with the potential to treat several diseases of complement dysregulation, as well as additional programs in preclinical development. Rallybio is headquartered in New Haven, Connecticut. For more information, please visit www.rallybio.com and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements that are based on our management's beliefs and assumptions and currently available information. All statements, other than statements of historical facts contained in this press release are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements concerning the timing of disclosure of preliminary PK and safety data for the sentinel participant in the RLYB212 Phase 2 trial, presenting or disclosing interim data from the FNAIT natural history study and the timing of such disclosure, whether RLYB212 will be an effective therapeutic approach for FNAIT, the timing of initiating the RLYB116 confirmatory PK/PD study and the date when data is available, including data for Cohorts 1 and 2, whether RLYB116 will be effective in treating a broad range of complement-mediated diseases, the timing of initiation of IND-enabling activities for REV102, and the timing of data in a preclinical model of later-onset HPP. The forward-looking statements in this press release are only predictions and are based largely on management's current expectations and projections about future events and financial trends that management believes may affect Rallybio's business, financial condition and results of operations. These forward-looking statements speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our ability to successfully initiate and conduct our planned clinical trials, including the RLYB116 confirmatory PK/PD study, and the Phase 2 trial for RLYB212, and complete such clinical trials and obtain results on our expected timelines, or at all, whether our cash resources will be sufficient to fund our operating expenses and capital expenditure requirements and whether we will be successful raising additional capital, our ability to enter into strategic partnerships or other arrangements, competition from other biotechnology and pharmaceutical companies, and those risks and uncertainties described in Rallybio's filings

with the U.S. Securities and Exchange Commission (SEC), including Rallybio's Quarterly Report on Form 10-Q for the period ended September 30, 2024, and subsequent filings with the SEC. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Except as required by applicable law, we are not obligated to publicly update or revise any forward-looking statements contained in this press release, whether as a result of any new information, future events, changed circumstances or otherwise.

Financial Tables

RALLYBIO CORPORATION

SELECTED CONDENSED CONSOLIDATED FINANCIAL INFORMATION

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

	FOR THE THREE MONTHS ENDED DECEMBER 31,		FOR THE YEAR ENDED DECEMBER 31,	
(in thousands, except share and per share amounts)	**2024**	**2023**	**2024**	**2023**
Revenue:				
Collaboration and license revenue	$ 38	$ —	$ 636	$ —
Total revenue	38	—	636	—
Operating expenses:				
Research and development	7,385	15,924	41,507	53,544
General and administrative	4,261	5,188	19,625	25,388
Total operating expenses	11,646	21,112	61,132	78,932
Loss from operations	(11,608)	(21,112)	(60,496)	(78,932)
Other income:				
Interest income	811	1,448	4,216	6,147
Other income	183	35	744	262
Total other income, net	994	1,483	4,960	6,409
Loss before equity in losses of joint venture	(10,614)	(19,629)	(55,536)	(72,523)
Loss on investment in joint venture	430	613	2,239	2,041
Net loss	$ (11,044)	$ (20,242)	$ (57,775)	$ (74,564)

Net loss per common share, basic and diluted	$ (0.25)	$ (0.50)	$ (1.33)	$ (1.84)
Weighted-average common shares outstanding, basic and diluted	44,660,619	40,639,567	43,544,824	40,447,388
Other comprehensive (loss) gain:				
Net unrealized (loss) gain on marketable securities	(101)	223	53	229
Other comprehensive (loss) gain	(101)	223	53	229
Comprehensive loss	$ (11,145)	$ (20,019)	$ (57,722)	$ (74,335)

Condensed Consolidated Balance Sheets

(Unaudited)

	DECEMBER 31, 2024	**DECEMBER 31, 2023**
(in thousands)		
Cash, cash equivalents and marketable securities	$ 65,511	$ 109,929
Total assets	68,108	115,620
Total liabilities	6,454	9,436
Total stockholders' equity	61,654	106,184

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