Rallybio Reports Second Quarter 2025 Financial Results and Provides Business Updates

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– Data Readouts from Cohort 1 and Cohort 2 of RLYB116 Confirmatory PK/PD Study on Track for 3Q and 4Q 2025, Respectively –

– Sold Interest in REV102 to Recursion Pharmaceuticals for Up to $25 Million, including an Upfront Equity Payment of $7.5 Million –

– Cash Runway into Mid-2027 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Aug. 7, 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 second quarter ended June 30, 2025, and provided an update on recent company developments.

“The second quarter marked a pivotal step forward as we advanced our lead program, RLYB116, into a confirmatory PK/PD study, which is an important milestone that reflects the strength of our science and the dedication of our team. Meanwhile, the strategic divestiture of a preclinical asset underscores our commitment to disciplined portfolio management, enabling us to sharpen our focus and strengthen the balance sheet as we continue to develop transformative therapies for patients and build long-term value for shareholders,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio. “With the RLYB116 confirmatory PK/PD study underway, we continue to look forward to the release of topline data from Cohort 1 and Cohort 2, expected in the third and fourth quarter of 2025, respectively.”

Recent Business Highlights and Upcoming Milestones:

Corporate Updates

- In July 2025, Rallybio announced that it entered into a definitive agreement to sell its interest in REV102, an ENPP1 inhibitor in preclinical development for the treatment of patients with hypophosphatasia (HPP), to its joint venture partner Recursion Pharmaceuticals (Recursion) for up to $25.0 million, including an upfront equity payment of $7.5 million and near-term milestones. The upfront payment extends Rallybio’s cash runway into the middle of 2027.

  In addition to the upfront payment, Rallybio is eligible to receive a contingent equity payment of $12.5 million upon the initiation of additional preclinical studies, and a $5.0 million cash milestone payment in connection with the initiation of dosing in a Phase 1 clinical study, as defined in the agreement. Rallybio is also eligible to receive low single-digit royalties on all future net sales by Recursion of products comprising or incorporating certain compounds developed as part of the joint venture. In addition, Rallybio may be eligible to receive certain payments in the event of Recursion’s sale of the REV102 program.

RLYB116 Program

- Rallybio announced the initiation of dosing in the RLYB116 confirmatory clinical pharmacokinetic/pharmacodynamic (PK/PD) study in June 2025. Results from Cohort 1 and Cohort 2 are anticipated in the third and fourth quarter of 2025, respectively. Data from this study are expected to demonstrate complete and sustained complement inhibition as well as improved tolerability of RLYB116.

- In June 2025, Rallybio also announced that the initial indication focus for RLYB116 will be on two hematologic conditions with significant unmet need: immune platelet transfusion refractoriness (PTR) and refractory antiphospholipid syndrome (APS).

RLYB332 Program

- Rallybio continues to evaluate plans for future development of RLYB332, a long-acting, monoclonal anti-matriptase-2 antibody that has the potential to be a best-in-class treatment for diseases of iron overload. Preclinical data has demonstrated superior impact on PD parameters relative to comparator molecules, including serum iron, unsaturated iron binding capacity (UIBC), and transferrin saturation (TSAT).

RLYB212 Program

- In April 2025, Rallybio announced the discontinuation of the RLYB212 program for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT). The Company’s decision to discontinue RLYB212 development was based on PK data from the Phase 2 clinical trial demonstrating the inability of the RLYB212 dose regimen to achieve predicted target concentrations, as well as the minimum target concentration required for efficacy. Safety follow-up of the sentinel participant in the Phase 2 trial will continue as specified in the clinical trial protocol.

Second Quarter 2025 Financial Results

- **Revenue:** Revenue was $0.2 million for the second quarter of 2025, compared to $0.3 million for the same period in 2024. The decrease in revenue for the second quarter of 2025 was related to 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 $6.1 million for the second quarter of 2025, compared to $12.9 million for the same period in 2024. The decrease in R&D expenses was primarily due to a decrease in development costs related to RLYB212, RLYB116 and other program candidates; offset by an increase related to payroll and personnel-related costs, largely related to the Company's workforce reduction announced in May 2025.

- **General & Administrative (G&A) Expenses:** G&A expenses were $4.2 million for the second quarter of 2025, compared to $4.4 million for the same period in 2024. The decrease in G&A expenses was primarily due to a decrease in professional fees and other general and administrative expenses; offset by an increase related to payroll and personnel-related costs, largely related to the 2025 workforce reduction.

- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net loss of $9.7 million, or $0.22 per common share, for the second quarter of 2025 compared to a net loss of $16.2 million, or $0.37 per common share, for the same period in 2024.

- **Cash Position:** As of June 30, 2025, cash, cash equivalents, and marketable securities were $45.7 million. Rallybio expects these funds, together with the upfront payment received from the sale of REV102 to Recursion in July 2025, will be sufficient to support operations into the middle of 2027.

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 pipeline of promising product candidates aimed at addressing diseases with unmet medical need in areas of complement dysregulation and hematology. The Company's lead program, RLYB116, is a differentiated C5 inhibitor with the potential to treat diseases of complement dysregulation, with an initial focus on immune platelet transfusion refractoriness (PTR) and refractory antiphospholipid syndrome (APS). Rallybio's pipeline also includes RLYB332, a preclinical long-acting matriptase-2 antibody for the treatment of diseases of iron overload. Rallybio is headquartered in New Haven, Connecticut. For more information, please visit www.rallybio.com and follow us on LinkedIn.

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 data for the RLYB116 confirmatory PK/PD study, including data for Cohorts 1 and 2, whether the PK/PD confirmatory study will demonstrate improved tolerability and complete and sustained complement inhibition, the potential commercial opportunity for RLYB116, the Company's eligibility for certain future payments in connection with the Company's sale to Recursion of the REV102 program, and the Company's cash runway. 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 conduct our clinical trials, including the RLYB116 PK/PD confirmatory study, 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 March 31, 2025, 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 JUNE 30,		FOR THE SIX MONTHS ENDED JUNE 30,	
(in thousands, except share and per share amounts)	**2025**	**2024**	**2025**	**2024**
Revenue:				
Collaboration and license revenue	$ 212	$ 299	$ 424	$ 299
Total revenue	212	299	424	299
Operating expenses:				
Research and development	6,074	12,946	$ 11,799	25,882
General and administrative	4,195	4,388	$ 8,352	11,239
Total operating expenses	10,269	17,334	20,151	37,121
Loss from operations	(10,057)	(17,035)	(19,727)	(36,822)
Other income:				
Interest income	523	1,143	$ 1,167	2,419
Other income	118	143	$ 292	310
Total other income, net	641	1,286	1,459	2,729
Loss before equity in losses of joint venture	(9,416)	(15,749)	(18,268)	(34,093)
Loss on investment in joint venture	287	487	$ 874	1,172
Net loss	$ (9,703)	$ (16,236)	$ (19,142)	$ (35,265)
Net loss per common share, basic and diluted	$ (0.22)	$ (0.37)	$ (0.43)	$ (0.83)
Weighted-average common shares outstanding, basic and diluted	44,841,140	44,128,059	44,808,055	42,450,837
Other comprehensive loss:				
Net unrealized loss on marketable securities	(30)	—	$ (51)	(86)
Other comprehensive loss	(30)	—	(51)	(86)
Comprehensive loss	$ (9,733)	$ (16,236)	$ (19,193)	$ (35,351)

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands)	JUNE 30, 2025	DECEMBER 31, 2024
Cash, cash equivalents and marketable securities	$ 45,749	$ 65,511
Total assets	51,003	68,108
Total liabilities	5,039	6,454
Total stockholders' equity	45,964	61,654

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