



Rallybio Reports First Quarter 2025 Financial Results and Provides Business Updates

May 8, 2025 at 8:00 AM EDT

– On Track to Initiate Dosing in RLYB116 Confirmatory PK/PD Study in 2Q 2025, with Multiple Data Readouts Anticipated in 2H 2025 –

– \$54.5 Million in Cash, Cash Equivalents, and Marketable Securities as of March 31, 2025 Provides Runway into 1H 2027 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--May 8, 2025-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today reported first quarter financial results for the period ended March 31, 2025, and provided an update on recent company developments.

"We are focused on advancing RLYB116 into a confirmatory pharmacokinetic/pharmacodynamic study this quarter, and believe that data from this study will demonstrate RLYB116's potential to be a best-in-class therapeutic for patients with complement-driven diseases," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Leveraging our team's deep expertise in the complement field, we are well-positioned to maximize RLYB116's transformative potential across multiple billion-dollar market opportunities. Additionally, we believe significant value resides within our preclinical pipeline, which includes REV102 and RLYB332. By advancing our innovative pipeline, we are committed to creating exceptional value for our shareholders while delivering life-changing therapies to patients who need them most."

Recent Business Highlights and Upcoming Milestones:

RLYB116 Program

- Rallybio is on track to initiate dosing in the RLYB116 confirmatory clinical pharmacokinetic/pharmacodynamic (PK/PD) study in the second quarter of 2025. Results from Cohort 1 (150 mg once weekly) and Cohort 2 (225 mg once weekly) are anticipated in the third and fourth quarter of 2025, respectively. Data from this study are expected to demonstrate complete and sustained complement inhibition with improved tolerability of RLYB116.

REV102 Program

- Investigational new drug application (IND)-enabling studies are underway for REV102, an ENPP1 inhibitor for the treatment of patients with hypophosphatasia (HPP), which is being developed through a joint venture with Recursion Pharmaceuticals. These studies are expected to support the initiation of a Phase 1 study in the second half of 2026.
- Presentation of data evaluating REV102 in a preclinical model of later-onset HPP is expected in the second half of 2025.

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.

Corporate Update

- Rallybio is implementing a 40% workforce reduction, representing nine positions, which will be substantially complete by the end of the second quarter of 2025. Rallybio estimates that the workforce reduction will result in aggregate charges of approximately \$1.7 million, primarily for one-time employee severance and benefit costs, and excluding share-based compensation expense.

First Quarter 2025 Financial Results

- **Revenue:** Revenue was \$0.2 million for the first quarter of 2025. There was no revenue for the first quarter of 2024. The increase in revenue for the first quarter of 2025 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 \$5.7 million for the first 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, in addition to a decrease in payroll and personnel-related costs, largely related to the workforce reduction in the first quarter of 2024.
- **General & Administrative (G&A) Expenses:** G&A expenses were \$4.2 million for the first quarter of 2025, compared to \$6.9 million for the same period in 2024. The decrease in G&A expenses was primarily due to a decrease in other general and administrative expenses in addition to lower payroll and personnel-related costs, largely related to the workforce reduction in the first quarter of 2024 and lower ongoing headcount in 2025 as compared to 2024.
- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net loss of \$9.4 million, or \$0.21 per common share, for the first quarter of 2025 compared to a net loss of \$19.0 million, or \$0.47 per common share, for the same period in 2024.
- **Cash Position:** As of March 31, 2025, cash, cash equivalents, and marketable securities were \$54.5 million. Rallybio expects these funds will be sufficient to support operations into the first half 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, hematology, and metabolic disorders. The Company's lead program, RLYB116, is a differentiated C5 inhibitor with the potential to treat diseases of complement dysregulation. Rallybio also has two programs in preclinical development, including REV102, an ENPP1 inhibitor for the treatment of patients with hypophosphatasia (HPP), and RLYB332, a 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](#) 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 initiating the RLYB116 confirmatory PK/PD study and the periods in which data is available, including data for Cohorts 1 and 2, whether the PK/PD confirmatory study will demonstrate improved tolerability and complete and sustained inhibition of terminal complement, whether RLYB116 will be effective in treating a broad range of complement-mediated diseases, the potential commercial opportunity for RLYB116, the potential value of Rallybio's pipeline, whether IND enabling studies for REV102 will support initiation of a Phase 1 study, the timing of initiation of a REV102 Phase 1 study, the timing of presenting data evaluating REV102 in a preclinical model of later-onset HPP, expected costs related to the workforce reduction and related charges, including the timing of such charges, 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 initiate and conduct our planned 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 Annual Report on Form 10-K for the period ended December 31, 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 MARCH 31,

(in thousands, except share and per share amounts)	2025	2024
Revenue:		
Collaboration and license revenue	\$ 212	\$ —
Total revenue	212	—
Operating expenses:		
Research and development	5,725	12,936
General and administrative	4,157	6,851
Total operating expenses	9,882	19,787
Loss from operations	(9,670)	(19,787)
Other income:		
Interest income	644	1,276
Other income	174	167
Total other income, net	818	1,443
Loss before equity in losses of joint venture	(8,852)	(18,344)
Loss on investment in joint venture	587	685
Net loss	\$ (9,439)	\$ (19,029)
Net loss per common share, basic and diluted	\$ (0.21)	\$ (0.47)
Weighted-average common shares outstanding, basic and diluted	44,774,602	40,773,615
Other comprehensive loss:		
Net unrealized loss on marketable securities	(21)	(86)
Other comprehensive loss	(21)	(86)
Comprehensive loss	\$ (9,460)	\$ (19,115)

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands)	MARCH 31, 2025	DECEMBER 31, 2024
Cash, cash equivalents and marketable securities	\$ 54,495	\$ 65,511
Total assets	57,983	68,108
Total liabilities	3,910	6,454
Total stockholders' equity	54,073	61,654

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