Rallybio Reports Third Quarter 2025 Financial Results and Provides Business Updates

November 6, 2025 at 8:00 AM EST

– RLYB116 Confirmatory PK/PD Study Data Expected in 4Q 2025 –

– Generated $20 Million from Sale of Interest in REV102 –

– Cash Runway Extended through 2027 –

NEW HAVEN, Conn.--(BUSINESS WIRE)--Nov. 6, 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 third quarter ended September 30, 2025, and provided an update on recent company developments.

“In the third quarter, we continued to execute with discipline and focus, advancing our lead program, RLYB116, and achieving a key clinical milestone with the completion of dosing in Cohort 1 in our confirmatory PK/PD Phase 1 study,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio. “In parallel, we strengthened our balance sheet with non-dilutive capital received from the sale of our interest in REV102. With the second cohort of the RLYB116 study progressing, we remain on track to report data in the fourth quarter of 2025 and are increasingly confident in RLYB116's potential to be an effective therapeutic. Our internal and external market assessments further validate the importance of advancing this program, as we plan for the next stage in development and in RLYB116’s potential to address serious unmet needs in complement-mediated diseases.”

Recent Business Highlights and Upcoming Milestones:

Corporate Updates

- In the third quarter of 2025, Rallybio generated a total of $20 million pursuant to its agreement with Recursion Pharmaceuticals for the sale of its interest in REV102, an investigational ENPP1 inhibitor in development for the treatment of hypophosphatasia (HPP). The total included $7.5 million from an upfront payment and $12.5 million related to the initiation of additional preclinical studies.

RLYB116 Program

- In September 2025, Rallybio completed dosing of Cohort 1 in the RLYB116 Phase 1 confirmatory pharmacokinetic/pharmacodynamic (PK/PD) clinical trial, which is planned for development in two hematologic conditions with significant unmet need: immune platelet transfusion refractoriness (PTR) and refractory antiphospholipid syndrome (APS).The Phase 1 study is designed to demonstrate complete and sustained complement inhibition as well as favorable tolerability. Data from Cohort 1 support the advancement of RLYB116 as a differentiated therapeutic and enables progression to Cohort 2. Rallybio is on track to report data from the study in the fourth quarter of 2025.

RLYB332 Program

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

Third Quarter 2025 Financial Results

- **Revenue:** Revenue was $0.2 million for the third quarter of 2025, compared to $0.3 million for the same period in 2024. The decrease in revenue for the third quarter of 2025 was related to the collaboration agreement with Johnson & Johnson in the third quarter of 2024 and the recognition of revenue related to the collaboration's performance obligations.
- **Research & Development (R&D) Expenses:** R&D expenses were $4.1 million for the third quarter of 2025, compared to $8.2 million for the same period in 2024. The decrease in R&D expenses were primarily due to a decrease in development costs related to RLYB212 and other program candidates, in addition to a decrease in payroll and personnel-related expenses, largely related to the Company's workforce reduction announced in May 2025; offset by an increase in development costs related to RLYB116.
- **General & Administrative (G&A) Expenses:** G&A expenses were $3.0 million for the third quarter of 2025, compared to $4.1 million for the same period in 2024. The decrease in G&A expenses were primarily due to a decrease in payroll and personnel-related expenses, largely related to lower headcount as compared to the same period in 2024.
- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net income of $16.0 million, or $0.36 per common share, for the third quarter of 2025 compared to a net loss of $11.5 million, or $0.26 per common share, for the same period in 2024.

- **Cash Position:** As of September 30, 2025, cash, cash equivalents, and marketable securities were $59.3 million. Rallybio expects that its cash, cash equivalents and marketable securities will be sufficient to support operations through 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 and refractory antiphospholipid syndrome. 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 dosing of Cohort 2 in the RLYB116 confirmatory PK/PD study and the periods in which data from the trial are expected to be available, 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 for future development of RLYB332, the potential for RLYB332 to be a best-in-class treatment for diseases of iron overload, 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 Quarterly Report on Form 10-Q for the period ended June 30, 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 Income (Loss)

(Unaudited)

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands, except share and per share amounts)	**2025**	**2024**	**2025**	**2024**
Revenue:				
Collaboration and license revenue	$ 212	$ 299	$ 636	$ 598
Total revenue	212	299	636	598
Operating expenses:				
Research and development	4,143	8,240	15,942	34,122
General and administrative	2,994	4,125	11,346	15,364
Total operating expenses	7,137	12,365	27,288	49,486

Loss from operations	(6,925)	(12,066)	(26,652)	(48,888)
Other income:				
Interest income	462	986	1,629	3,405
Gain on sale of joint venture and other income	22,479	251	22,771	561
Total other income, net	22,941	1,237	24,400	3,966
Gain (loss) before equity in losses of joint venture	16,016	(10,829)	(2,252)	(44,922)
Loss on investment in joint venture	—	637	874	1,809
Net income (loss)	$ 16,016	$ (11,466)	$ (3,126)	$ (46,731)
Net income (loss) per common share, basic and diluted	$ 0.36	$ (0.26)	$ (0.07)	$ (1.08)
Weighted-average common shares outstanding, basic and diluted	45,058,591	44,593,221	44,892,485	43,170,177
Other comprehensive gain (loss):				
Net unrealized gain (loss) on marketable securities	7	240	(44)	154
Other comprehensive gain (loss)	7	240	(44)	154
Comprehensive gain (loss)	$ 16,023	$ (11,226)	$ (3,170)	$ (46,577)

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands)	**SEPTEMBER 30, 2025**	**DECEMBER 31, 2024**
Cash, cash equivalents and marketable securities	$ 59,319	$ 65,511
Total assets	67,661	68,108
Total liabilities	4,627	6,454
Total stockholders' equity	63,034	61,654

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Source: Rallybio Corporation