Rallybio Reports Second Quarter 2023 Financial Results and Provides Business Updates

-- RLYB212 Phase 1b Proof-of-Concept Study Results Presented at the 31st Congress of the International Society of Thrombosis and Haemostasis (ISTH) in June 2023 --

-- RLYB212 Phase 1 Multiple Dose Cohort Study Results Expected in 4Q 2023 --

-- Initial Data from RLYB116 Phase 1 Multiple Ascending Dose Study Including Safety, PK and PD Expected in 4Q 2023 --

-- $137.8 million cash, cash equivalents and marketable securities as of June 30, 2023; Provides Runway into 1Q 2025 --

NEW HAVEN, Conn. August 8, 2023-- Rallybio Corporation (Nasdaq: RLYB) today reported financial results for the second quarter ended June 30, 2023 and provided an update on recent program and corporate developments.

"We continue to make significant progress across our portfolio. We were pleased to have results from the Phase 1b proof-of-concept study for RLYB212, our anti-HPA-1a monoclonal antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), presented at the International Society on Thrombosis and Haemostasis Congress in June. With both dose groups in the study meeting the proof-of-concept criteria of at least 90% reduction in mean platelet elimination half-life, these results continue to support the potential use of subcutaneous RLYB212 for the prevention of HPA-1a alloimmunization and FNAIT. In the fourth quarter of 2023, we plan to complete the toxicology program for RLYB212, and share the results from the multiple dose cohort of our ongoing Phase 1 study for RLYB212. In parallel, we expect to initiate regulatory discussions which will support the initiation of a Phase 2 dose confirmation study in pregnant women at higher risk of FNAIT for RLYB212 in the second half of 2024," said Stephen Uden, M.D., Chief Executive Officer of Rallybio.

Dr. Uden continued, "We continue to advance our multiple ascending dose Phase 1 study of RLYB116, an inhibitor of complement component 5 (C5) and expect to share initial data from this study, as well as details on our initial indication strategy for RLYB116, in the fourth quarter of 2023. As we continue to fortify our position as a leader in the development of transformative medicines for underserved rare diseases, we believe our existing capital will allow us to advance our portfolio through upcoming milestones."

Maternal Fetal Blood Disorders

Results from the Phase 1b proof-of-concept study of RLYB212, an anti-HPA-1a monoclonal antibody in development for the prevention of FNAIT, were presented at the 31st Congress of the International Society for Thrombosis and Haemostasis in June 2023. In this study, subcutaneous RLYB212 administration produced a dose-dependent, rapid and complete elimination of transfused HPA-1a positive platelets in HPA-1a negative subjects, with both dose groups meeting the pre-specified proof-of-concept criteria of ≥ 90% reduction in mean platelet elimination half-life. Mean platelet elimination half-life was 5.8 hours (0.09mg dose) and 1.5 hours (0.29mg dose) for RLYB212 compared to 71.7 hours for placebo. Consistent with previously reported data, RLYB212 was well-tolerated with no reports of serious or severe adverse events.

The Company expects to achieve the following milestones in the fourth quarter of 2023 for RLYB212:

- Complete the comprehensive toxicology program for RLYB212, including maternal-fetal toxicology.

- Report results from the multiple dose cohort of the Phase 1 safety and pharmacokinetic study of RLYB212. This multiple dose cohort, which was initiated in the first quarter of 2023, is designed to evaluate safety and pharmacokinetics of subcutaneous RLYB212 based on repeat dosing over 12 weeks.

Rallybio expects to initiate a Phase 2 dose confirmation study for RLYB212 in the second half of 2024 in order to confirm the RLYB212 dose regimen in pregnant women at higher risk of FNAIT. Following completion of the Phase 2 dose confirmation study and consultation with regulatory authorities, Rallybio expects to initiate a Phase 3 registrational study.

The Company also continues to advance the FNAIT natural history alloimmunization study. In June 2023, the Company announced approximately 4,500 women have been screened to date and an estimated 7,600 women are planned to be screened by the end of 2023. The Company expects screening for the natural history study to continue simultaneously with execution of the Phase 2 study.

Complement Dysregulation

The Phase 1 multiple ascending dose study of RLYB116, a novel, potentially long-acting, subcutaneously injected inhibitor of C5 in development for the treatment of patients with complement-related diseases continues to advance. This single-blind, dose escalation, placebo-controlled study is designed to evaluate the safety, pharmacokinetics, and pharmacodynamics of RLYB116 in healthy participants.

The Company expects to report initial data from this study in the fourth quarter of 2023 along with its initial plans for potential indications for which RLYB116 could be developed.

In July 2023, Rallybio announced the acceptance of an abstract for a poster that will report data from the Phase 1 first-in-human single ascending dose clinical study of RLYB116. The poster will be presented at the 29th International Complement Workshop, which will take place in Newcastle, UK from August 31 to September 5, 2023.

Corporate Updates

On August, 1, 2023, Stephen Uden, M.D. became Chief Executive Officer of Rallybio, and a member of the Board of Directors. Dr. Uden remains President of Rallybio. He succeeded Martin Mackay, Ph.D. as Chief Executive Officer. Dr. Mackay was appointed Executive Chairman effective on August 1, 2023. As Executive Chairman, Dr. Mackay remains a full-time employee and is actively involved with the Company, with a particular focus on company strategy, investor relations and related activities.

Second Quarter 2023 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $13.1 million for the second quarter of 2023, compared to $10.1 million for the same period in 2022. The increase in R&D expenses was primarily due to an increase in costs to advance RLYB212 and RLYB116 and an increase in R&D related headcount costs, including share-based compensation expense, as compared to the prior year.
- **General & Administrative (G&A) Expenses:** G&A expenses were $7.0 million for the second quarter of 2023, compared to $7.5 million for the same period in 2022. The

decrease in G&A expenses was primarily due to a decrease in G&A related payroll and personnel-related costs, including share-based compensation expense.

- **Net Loss and Net Loss Per Common Share:** Net loss was $18.6 million for the second quarter of 2023, or net loss per common share of $0.46 compared to a net loss of $17.6 million, or net loss per common share of $0.57 for the second quarter of 2022.
- **Cash Position:** As of June 30, 2023, cash, cash equivalents and marketable securities were $137.8 million.

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, an inhibitor of complement component 5 (C5), 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 with an additional facility at the University of Connecticut's Technology Incubation Program in Farmington, 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 on 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 initiation, progress, substance, design and timing of our planned or ongoing studies for RLYB212 and RLYB116, including the planned RLYB212 Phase 2 and Phase 3 studies, the timing of the availability of data from such studies, our expectations regarding reporting of data from such studies, and our expectations regarding the usefulness of data from such studies, the timing of the availability of data from the RLYB212 toxicology program and our expectations regarding the usefulness of such data, the potential markets for RLYB212 and RLYB116, the potential indications for which RLYB116 could be developed and our plans for presenting such potential indications, our estimates of our capital requirements and the sufficiency thereof, our ability to advance our portfolio, our plans for development of our inhibitor of C5 for the treatment of ophthalmic disorders, and our plans for development activities with our strategic collaboration partners. 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 FNAIT natural history study, and the Phase 1 and 1b clinical trials for RLYB212 and the Phase 1 study for RLYB116, 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 identify new product candidates and successfully acquire such product candidates from third parties, our ability to enter into strategic partnerships or other arrangements, including such an arrangement

for the development of our inhibitor of C5 for the treatment of ophthalmic disorders, 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, 2023, 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)

(in thousands, except share and per share amounts)	FOR THE THREE MONTHS ENDED JUNE 30, 2023	FOR THE THREE MONTHS ENDED JUNE 30, 2022	FOR THE SIX MONTHS ENDED JUNE 30, 2023	FOR THE SIX MONTHS ENDED JUNE 30, 2022
Operating expenses:				
Research and development	$ 13,130	$ 10,138	$ 24,332	$ 17,786
General and administrative	6,953	7,477	14,125	14,147
Total operating expenses	20,083	17,615	38,457	31,933
Loss from operations	(20,083)	(17,615)	(38,457)	(31,933)
Other income:				
Interest income	1,608	270	3,154	367
Other income	62	100	135	213
Total other income, net	1,670	370	3,289	580
Loss from continuing operations	(18,413)	(17,245)	(35,168)	(31,353)
Loss on investment in joint venture	217	338	780	728
Net loss	$ (18,630)	$ (17,583)	$ (35,948)	$ (32,081)
Net loss per common share, basic and diluted	$ (0.46)	$ (0.57)	$ (0.89)	$ (1.05)
Weighted-average common shares outstanding, basic and diluted	40,363,902	30,588,931	40,306,715	30,453,913
Other comprehensive loss:				
Net unrealized loss on marketable	(211)	(249)	(58)	(371)
Other comprehensive loss	(211)	(249)	(58)	(371)
Comprehensive loss	$ (18,841)	$ (17,832)	$ (36,006)	$ (32,452)

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	JUNE 30, 2023	DECEMBER 31, 2022
Cash, cash equivalents and marketable securities	$ 137,838	$ 168,994
Total assets	147,576	180,435
Total liabilities	8,319	11,118
Total stockholders' equity	139,257	169,317

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