Rallybio Reports First Quarter 2023 Financial Results

May 9, 2023 at 8:00 AM EDT

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

-- Phase 1 Multiple Dose Cohort RLYB212 Study Initiated in 1Q 2023; Data Expected in 4Q 2023 --

-- Phase 1 Multiple Ascending Dose Study of RLYB116 Continues to Progress; Safety, PK and PD Data Expected in 4Q 2023 --

-- $150.4 million cash, cash equivalents and marketable securities as of March 31, 2023; Provides Runway into 1Q 2025 --

NEW HAVEN, Conn.--(BUSINESS WIRE)--May 9, 2023-- Rallybio Corporation (Nasdaq: RLYB) today reported financial results for the first quarter ended March 31, 2023 and provided an update on recent program and corporate developments.

"We continue to progress our pipeline toward planned upcoming milestones. We recently announced that the Phase 1b proof-of-concept study results for RLYB212, our anti-HPA-1a monoclonal antibody product candidate for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), will be presented at the International Society on Thrombosis and Haemostasis Congress. While physicians have high awareness of the catastrophic impact of FNAIT and a desire to proactively treat expectant at-risk mothers, there are currently no approved therapies available to the thousands of women impacted each year. We look forward to sharing our Phase 1b data in June, as we continue to educate healthcare providers and their patients on the potential opportunity for RLYB212. We also continue to enroll the multiple dose cohort of our ongoing Phase 1 trial, and expect to report results from this cohort in the fourth quarter of 2023. Later this year, we expect to provide additional details regarding our clinical development plans for RLYB212," said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio.

Dr. Mackay continued, "We continue to advance efforts across our programs in complement dysregulation, hematology and metabolic disorders. Our multiple ascending dose Phase 1 study of RLYB116, an inhibitor of complement component 5 (C5), also continues to progress and we expect to share initial data from this study, as well as details on our initial indication strategy, in the fourth quarter of 2023. As we continue our development of potentially transformative medicines for underserved rare diseases, we believe our existing capital will enable us to advance our portfolio through upcoming milestones and into our next phase of growth as a company."

Recent Business Highlights and Upcoming Milestones:

Maternal Fetal Blood Disorders

In the first quarter of 2023, Rallybio initiated testing in the multiple dose cohort of its Phase 1 trial for RLYB212, an anti-HPA-1a monoclonal antibody being developed for the prevention of FNAIT. This portion of the Phase 1 study will evaluate safety and pharmacokinetics of RLYB212 based on repeat subcutaneous dosing over 12 weeks and the Company expects results from this cohort of subjects in the fourth quarter of 2023.

Rallybio announced in April 2023 the acceptance of an abstract for RLYB212 reporting results from the Phase 1b proof-of-concept study for presentation at the 31st Congress of the ISTH, which will take place in Montreal from June 24-28, 2023.

Rallybio also announced in April 2023 that clinical proof-of-concept results for RLYB211, an anti-HPA-1a polyclonal antibody for the prevention of FNAIT, were published in the April issue of the peer-reviewed journal, *Journal of Thrombosis and Haemostasis.* The results demonstrated the prophylactic potential of an HPA-1a antibody to prevent HPA-1a alloimmunization and occurrence of FNAIT. Given the advantages of small volume subcutaneous dosing of RLYB212 as compared to RLYB211 and the expected manufacturing and supply efficiencies for RLYB212, Rallybio announced in March 2023 that the Company will not continue development of RLYB211.

The Company continues to advance the FNAIT natural history alloimmunization study. This non-interventional study is designed to inform on the frequency of women at higher risk for FNAIT across a broad population of pregnant women of different racial and ethnic characteristics, and the occurrence of HPA-1a alloimmunization in these women. The Company expects that the data from this study will contribute to a control dataset for a future single armed registration trial for RLYB212.

Complement Dysregulation

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

The Company currently expects initial data from this Phase 1 study in the fourth quarter of 2023. In parallel with ongoing clinical activities, the Company has been evaluating potential indications for which RLYB116 could be developed and intends to provide its initial plans in conjunction with the release of the Phase 1 data, currently expected in the fourth quarter of 2023.

In February 2023, Rallybio and EyePoint Pharmaceuticals, Inc. (EyePoint) announced a research collaboration to explore and assess the viability of utilizing Rallybio's inhibitor of C5 in EyePoint's Durasert ® technology for sustained intraocular delivery. The initial focus will be on geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss.

First Quarter 2023 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $11.2 million for the first quarter of 2023, compared to $7.6 million for the same period in 2022. R&D expenses for the first quarter of 2023 increased 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 $7.2 million for the first quarter of 2023, compared to $6.7 million for the same period in 2022. The increase in G&A expenses was primarily due to additional G&A related payroll and personnel-related costs, including share-based compensation expense.
- **Net Loss and Net Loss Per Common Share:** Net loss was $17.3 million for the first quarter of 2023, or net loss per common share of $0.43 compared to a net loss of $14.5 million, or net loss per common share of $0.48 for the first quarter of 2022.
- **Cash Position:** As of March 31, 2023, cash, cash equivalents and marketable securities were $150.4 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, a C5 complement 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 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.

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, 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 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, including EyePoint. 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 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 Annual Report on Form 10-K for the period ended December 31, 2022, 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)	**2023**	**2022**

Operating expenses:		
Research and development	$ 11,202	$ 7,648
General and administrative	7,172	6,670
Total operating expenses	18,374	14,318
Loss from operations	(18,374)	(14,318)
Other income (expenses):		
Interest income	1,546	97
Other income	73	113
Total other income, net	1,619	210
Loss from continuing operations	(16,755)	(14,108)
Loss on investment in joint venture	563	390
Net loss	$ (17,318)	$ (14,498)
Net loss per common share, basic and diluted	$ (0.43)	$ (0.48)
Weighted-average common shares outstanding, basic and diluted	40,248,893	30,318,405
Other comprehensive income (loss):		
Net unrealized income (loss) on marketable securities	153	(122)
Other comprehensive income (loss)	153	(122)
Comprehensive loss	$ (17,165)	$ (14,620)

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	**MARCH 31, 2023**	**DECEMBER 31, 2022**
Cash, cash equivalents and marketable securities	$ 150,389	$ 168,994
Total assets	162,318	180,435
Total liabilities	7,121	11,118

Total stockholders' equity	155,197	169,317

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