Rallybio Reports Third Quarter 2023 Financial Results and Provides Business Updates

November 9, 2023 at 8:00 AM EST

-- RLYB212 Phase 1 Multiple Dose Cohort Complete and on Track for 4Q 2023 Data Release --

-- Initial Data from RLYB116 Phase 1 Multiple Ascending Dose Study Including Safety, PK and PD on Track for 4Q 2023 Release --

-- $121.4 million cash, cash equivalents and marketable securities as of September 30, 2023; Provides Runway into 1Q 2025 --

NEW HAVEN, Conn.--(BUSINESS WIRE)--Nov. 9, 2023-- Rallybio Corporation (Nasdaq: RLYB) today reported financial results for the third quarter ended September 30, 2023 and provided an update on recent program and corporate developments.

"We are pleased with the continued progress across our portfolio in recent months, further demonstrating the ability of our team to efficiently advance clinical trials across diverse therapeutic areas. Prior to the end of 2023, we expect to finalize the toxicology package for RLYB212, our anti-HPA-1a monoclonal antibody for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), to support our planned Phase 2 and Phase 3 studies in pregnant women. In addition, we have completed the multiple dose cohort of our ongoing Phase 1 study for RLYB212 and have initiated regulatory discussions for RLYB212 to support the initiation of a Phase 2 dose confirmation study in pregnant women at higher risk for FNAIT. We also look forward to sharing more about the ongoing FNAIT natural history study at the upcoming American Society of Hematology Annual Meeting in December," said Stephen Uden, M.D., Chief Executive Officer of Rallybio.

Dr. Uden continued, "Our multiple ascending dose Phase 1 study for RLYB116, an inhibitor of complement component 5 (C5), remains on track and we expect to share initial data from this study, including our indication strategy, prior to the end of 2023. In parallel, we continue to advance our preclinical programs albeit with a focus on capital conservation and believe our existing capital will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2025."

Maternal Fetal Blood Disorders
Rallybio expects to achieve the following milestones in the fourth quarter of 2023 for RLYB212, an anti-HPA-1a monoclonal antibody being developed for the prevention of FNAIT:

- Finalize toxicology package for RLYB212, including maternal-fetal toxicology to support our planned Phase 2 and Phase 3 studies in pregnant women.
- Disclose preliminary data for the multiple dose cohort of the Phase 1 safety and pharmacokinetic study of RLYB212.
- Poster presentation of abstract for the ongoing natural history study at the 65th American Society of Hematology Annual Meeting in December 2023.
- On track to screen 7,600 women for the natural history study by the end of 2023.

The Company also continues to advance the FNAIT natural history 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 screening for the natural history study to continue simultaneously with execution of the Phase 2 dose confirmation study. The Phase 2 study for RLYB212 is expected to initiate in the second half of 2024 and is designed to confirm the dose regimen for RLYB212 in pregnant women at higher risk of FNAIT.

Complement Dysregulation
Rallybio remains on track to report initial data in the fourth quarter of 2023 from the Phase 1 multiple ascending dose (MAD) study of RLYB116, a novel, potentially long-acting, subcutaneously injected 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. In parallel with the initial data from this study, Rallybio also intends to discuss its plans for potential indications for which RLYB116 could be developed.

In September 2023, clinical data from the Phase 1 first-in-human single ascending dose (SAD) clinical study of RLYB116 were presented in a poster at the 29th International Complement Workshop. The data demonstrated that single-dose administration of RLYB116 at the two higher doses of 100 mg and 300 mg resulted in maximum exposures of greater than 1 µM and 3 µM, respectively, and greater than 99% reductions in free C5 concentrations. Subcutaneously administered RLYB116 was observed to be generally well-tolerated as a single 100 mg or 300 mg dose, with mild to moderate adverse events and no drug-related serious adverse events.

Third Quarter 2023 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $13.3 million for the third quarter of 2023, compared to $12.1 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 RLYB331 and an increase in R&D related headcount costs, including share-based compensation expense, as compared to the prior year. These costs were offset by a decrease in R&D costs related to RLYB116.

- **General & Administrative (G&A) Expenses:** G&A expenses were $6.1 million for the third quarter of 2023, compared to $6.8 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 and director and officer insurance premiums; offset by increases in other general and administrative related expenses.

- **Net Loss and Net Loss Per Common Share:** Net loss was $18.4 million for the third quarter of 2023, or net loss per common share of $0.45 compared to a net loss of $18.4 million, or net loss per common share of $0.60 for the third quarter of 2022.

- **Cash Position:** As of September 30, 2023, cash, cash equivalents and marketable securities were $121.4 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, 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, including for the Phase 1 RLYB212 study and the multiple ascending dose RLYB116 study, 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 June 30, 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)

	FOR THE THREE MONTHS ENDED SEPTEMBER 30,		FOR THE NINE MONTHS ENDED SEPTEMBER 30,	
(in thousands, except share and per share amounts)	**2023**	**2022**	**2023**	**2022**

Operating expenses:				
Research and development	$ 13,288	$ 12,110	$ 37,620	$ 29,896
General and administrative	6,075	6,750	20,200	20,897
Total operating expenses	19,363	18,860	57,820	50,793
Loss from operations	(19,363)	(18,860)	(57,820)	(50,793)
Other income:				
Interest income	1,545	525	4,699	892
Other income	92	98	227	311
Total other income, net	1,637	623	4,926	1,203
Loss before equity in losses of joint venture	(17,726)	(18,237)	(52,894)	(49,590)
Loss on investment in joint venture	648	133	1,428	861
Net loss	$ (18,374)	$ (18,370)	$ (54,322)	$ (50,451)
Net loss per common share, basic and diluted	$ (0.45)	$ (0.60)	$ (1.35)	$ (1.65)
Weighted-average common shares outstanding, basic and diluted	40,531,497	30,777,797	40,382,625	30,562,723
Other comprehensive gain (loss):				
Net unrealized gain (loss) on marketable securities	64	(63)	6	(434)
Other comprehensive gain (loss)	64	(63)	6	(434)
Comprehensive loss	$ (18,310)	$ (18,433)	$ (54,316)	$ (50,885)

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands)	**SEPTEMBER 30, 2023**	**DECEMBER 31, 2022**
Cash, cash equivalents and marketable securities	$ 121,384	$ 168,994
Total assets	133,194	180,435
Total liabilities	9,613	11,118

Total stockholders' equity	123,581	169,317

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Investor
Ami Bavishi
Head of Investor Relations and Corporate Communications
(475) 47-RALLY (Ext. 282)
abavishi@rallybio.com

Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannah.deresiewicz@sternir.com

Media
Jorge Gaeta
Mission North
(516) 430-7659
Rallybio@missionnorth.com

Source: Rallybio Corporation