UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 12, 2024

RALLYBIO CORPORATION

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40693**	**85-1083789**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

234 Church Street, Suite 1020 New Haven, Connecticut	**06510**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: 203 859-3820

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RLYB	NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 12, 2024, Rallybio Corporation issued a press release announcing its financial results for the fiscal quarter and year ended December 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on March 12, 2024 regarding financial results for the fiscal quarter and year ended December 31, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

RALLYBIO CORPORATION

Date: March 12, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Exhibit 99.1

Rallybio Reports Fourth Quarter and Full Year 2023 Financial Results

-- Received Protocol Assistance Feedback from European Medicines Agency on the Phase 2 Study for RLYB212; Company to Proceed Forward with Clinical Trial Application Process in Europe --

-- Phase 2 Dose Confirmation Study for RLYB212 in Pregnant Women at Higher Risk for FNAIT Expected to Initiate in 2H 2024 --

-- $109.9 million Cash, Cash Equivalents and Marketable Securities as of December 31, 2023; Provides Runway into Mid-2026 --

NEW HAVEN, Conn. March 12, 2024-- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases, today reported financial results for the fourth quarter and full year ended December 31, 2023 and provided an update on recent program and corporate developments.

“We are encouraged by the continued progress we made across our portfolio throughout 2023. Following our February 2024 announcement regarding the prioritization of our portfolio and reorganization of our operations, we believe our existing capital will fund our revised operating plan into the middle of mid-2026 and intend to focus our efforts in 2024 on our clinical-stage programs, RLYB212 and RLYB116. We have received feedback from the European Medicines Agency for RLYB212 and are pleased to now move forward with the clinical trial application process in Europe where we will conduct the Phase 2 dose confirmation study for RLYB212 in pregnant women at higher risk for FNAIT. The Phase 2 study remains on track to initiate in the second half of 2024,” said Stephen Uden, M.D., Chief Executive Officer of Rallybio.

Dr. Uden continued, “In parallel, the manufacturing work for RLYB116 is ongoing and we are encouraged by the data indicating the potential to achieve improved tolerability at higher doses. We expect to complete this work and provide an update on the development plan for RLYB116 in the second half of 2024. We also remain committed to advancing our preclinical programs to the next milestone and will seek alternative options to advance and or finance these programs with a goal of realizing the value of these programs.”

Recent Business Highlights and Upcoming Milestones:

Corporate Updates

In February 2024, Rallybio announced a prioritization of its portfolio and 45% workforce reduction to focus the Company’s resources on its two Phase 2 ready assets, RLYB212, a novel human monoclonal anti-HPA-1a antibody in development for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), and RLYB116, a once-weekly, low volume subcutaneously injected inhibitor of complement component 5 (C5) in development for patients with complement mediated diseases. With these changes, Rallybio announced that the Company expects its cash runway to extend into the middle of 2026.

The workforce reduction included 19 roles and will be substantially complete by the end of the first quarter of 2024. Rallybio estimates that the workforce reduction will result in aggregate charges of approximately $3.3 million primarily for one-time employee severance and benefit costs, excluding share-based compensation expense.

Maternal Fetal Blood Disorders

In November 2023, Rallybio announced preliminary data from the completed multiple dose cohort of the Phase 1 safety and pharmacokinetics (PK) study for RLYB212. The Phase 1 multiple dose cohort for RLYB212 was initiated in the first quarter of 2023 to evaluate the safety and PK of subcutaneous (SC) RLYB212 based on repeat dosing over 12 weeks. The preliminary data demonstrated that multiple dose PK were consistent both within and between subjects and, together with the Company's clinical pharmacology modeling predictions, support a once monthly dosing regimen for the planned Phase 2 study in pregnant women at higher risk for FNAIT. Consistent with previously reported data, RLYB212 was observed to be generally well-tolerated with no reports of injection site reactions or serious adverse events.

Rallybio announced today that the Company has received Protocol Assistance Feedback from the European Medicines Agency (EMA) on the RLYB212 Phase 2 study, and the Company is now moving forward with Clinical Trial Applications to support conduct of the Phase 2 study in Europe. Rallybio continues to expect to initiate the Phase 2 dose confirmation study in pregnant women at higher risk for FNAIT in the second half of 2024.

The Company continues to screen in the FNAIT natural history alloimmunization study, a non-interventional study designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population. The Company expects screening for the natural history study to continue simultaneously with execution of the Phase 2 dose confirmation study. As of March 1, 2024, Rallybio has screened approximately 9,400 women in the natural history study, and expects to screen between 20,000 and 30,000 women in the study.

Complement Dysregulation

In December 2023, Rallybio announced preliminary Phase 1 multiple ascending dose data for RLYB116. Results demonstrated that a 100 mg low volume once-a-week dose of subcutaneously administered RLYB116 achieved sustained mean reductions in free C5 of greater than 93%. In addition, RLYB116 administered as a 100 mg once-a-week dose was observed to be generally well tolerated with injection site reaction as the most common adverse event (AE) in the cohort, occurring in 60% of the participants in the cohort. All AEs with the 100 mg weekly dose were mild in severity.

While the exposure concentrations of RLYB116 demonstrated in the Phase 1 study are expected to be suitable for the treatment of patients with generalized myasthenia gravis, the Company believes ongoing manufacturing enhancements will enable higher exposure to RLYB116, supporting the treatment of patients with a broader range of complement-mediated diseases, including paroxysmal nocturnal hemoglobinuria and antiphospholipid syndrome. The manufacturing work is progressing and Rallybio is encouraged by the data indicating the potential to achieve improved tolerability at higher doses.

Rallybio continues to expect to complete this manufacturing work in the second half of 2024 and to provide an update on the development plan for RLYB116 at that time.

Rallybio, together with its partner EyePoint Pharmaceuticals, Inc., continue to evaluate sustained delivery of Rallybio's inhibitor of C5 using EyePoint's proprietary technology for sustained intraocular drug delivery. Rallybio and EyePoint expect to provide an update on this collaboration in the first half of 2024.

Preclinical Programs

The revised operating plan will fund preclinical program activities to important 2024 milestones, as described below. Beyond achievement of these milestones, Rallybio will seek alternative options to further advance these programs, including additional partnerships and other forms of non-dilutive financing.

- **RLYB331, Matriptase-2 (MTP-2) Inhibitor:** Completion of the ongoing preclinical activities, with data expected in the first half of 2024.
- **ENPP1 Inhibitor, Exscientia Partnership:** Lead AI-designed compounds enter candidate selection process in the second half of 2024.
- **AbCellera Partnership:** Advancement of discovery efforts to the next research milestone in the second half of 2024.

Fourth Quarter and Full Year 2023 Financial Results

- **Research & Development (R&D) Expenses:** R&D expenses were $15.9 million for the fourth quarter of 2023, compared to $10.8 million for the same period in 2022. R&D expenses for the fourth quarter 2023 increased primarily due to an increase in costs to advance RLYB212, RLYB116 and RLYB331 as compared to the prior year. R&D expenses were $53.5 million for the year ended December 31, 2023 compared to $40.7 million for the year ended December 31, 2022. R&D expenses for the year ended December 31, 2023 increased primarily due to an increase in costs to advance RLYB212, RLYB116 and RLYB331 and additional 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 asset acquisition costs and R&D costs related to RLYB114.

- **General & Administrative (G&A) Expenses:** G&A expenses were $5.2 million for the fourth quarter of 2023, compared to $6.3 million for the same period in 2022. G&A expenses for the fourth quarter of 2023 decreased primarily due to a decrease in payroll and personnel-related costs, lower director and officer insurance premiums and lower other general and administrative related expenses as compared to the prior year. G&A expenses were $25.4 million for the year ended December 31, 2023 compared to $27.2 million for the year ended December 31, 2022. The decrease in G&A expenses for the year ended December 31, 2023 was primarily due to a decrease in payroll and personnel-related costs and lower 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 $20.2 million for the fourth quarter of 2023, or net loss per common share of $0.50 compared to a net loss of $16.2 million, or net loss per common share of $0.46 for the fourth quarter of 2022. Net loss was $74.6 million, or net loss per share of $1.84, for the year ended December 31, 2023 compared to $66.7 million, or net loss per share of $2.09, for the year ended December 31, 2022.

- **Cash Position:** As of December 31, 2023, cash, cash equivalents, and marketable securities were $109.9 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. 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 timing of initiation of the Phase 2 dose confirmation study for RLYB212, the release of screening numbers of women in the natural history study, whether the results of the natural history study and the planned Phase 2 dose confirmation study will be sufficient to support design and implementation of a Phase 3 registrational study for RLYB212, whether the manufacturing work for RLYB116 will be timely completed or successful, our expectations regarding the usefulness of data from our clinical studies, the timing of achieving milestones in 2024 for our preclinical programs, the likelihood that Rallybio will be successful in developing RLYB212, RLYB116, or any of our other product candidates, our ability to successfully identify and implement alternative and acceptable options to further advance our programs, expected costs related to the workforce reduction and related charges, including the timing of such charges, the expected use of operating cost savings associated with the updated operating plan and the timing, our estimates of our capital requirements and the sufficiency thereof, our ability to advance our portfolio, and our 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 FNAIT natural history study, and the Phase 2 clinical trial for RLYB212, and complete such clinical trial 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 RLYB114, 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 September 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 DECEMBER 31,		FOR THE YEAR ENDED DECEMBER 31	
(in thousands, except share and per share amounts)	**2023**	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 15,924	$ 10,793	$ 53,544	$ 40,689
General and administrative	5,188	6,298	25,388	27,195
Total operating expenses	21,112	17,091	78,932	67,884
Loss from operations	(21,112)	(17,091)	(78,932)	(67,884)
Other income:				
Interest income	1,448	1,071	6,147	1,963
Other income	35	31	262	342
Total other income, net	1,483	1,102	6,409	2,305
Loss before equity in losses of joint venture	(19,629)	(15,989)	(72,523)	(65,579)
Loss on investment in joint venture	613	214	2,041	1,075
Net loss	$ (20,242)	$ (16,203)	$ (74,564)	$ (66,654)
Net loss per common share, basic and diluted	$ (0.50)	$ (0.46)	$ (1.84)	$ (2.09)
Weighted-average common shares outstanding, basic and diluted	40,639,567	35,516,630	40,447,388	31,821,311
Other comprehensive gain (loss):				
Net unrealized gain (loss) on marketable securities	223	220	229	(214)
Other comprehensive gain (loss)	223	220	229	(214)
Comprehensive loss	$ (20,019)	$ (15,983)	$ (74,335)	$ (66,868)

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	DECEMBER 31, 2023	DECEMBER 31, 2022
Cash, cash equivalents and marketable securities	$ 109,929	$ 168,994
Total assets	115,620	180,435
Total liabilities	9,436	11,118
Total stockholders' equity	106,184	169,317

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