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): May 09, 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 May 9, 2024, Rallybio Corporation issued a press release announcing its financial results for the quarter ended March 31, 2024. 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 May 9, 2024 regarding financial results for the fiscal quarter ended March 31, 2024
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: May 9, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Rallybio Reports First Quarter 2024 Financial Results and Provides Business Updates

– On Track to Initiate RLYB212 Phase 2 Dose Confirmation Trial in Pregnant Women at Higher Risk of FNAIT in 2H 2024 –

– $94.2 Million in Cash, Cash Equivalents, and Marketable Securities as of March 31, 2024; Provides Runway into Mid-2026 –

NEW HAVEN, Conn., May 9, 2024 -- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today reported first quarter financial results for the period ended March 31, 2024 and provided an update on recent company developments.

“This year is off to a strong start as we continue to progress towards the initiation of our Phase 2 dose confirmation trial for RLYB212 in pregnant women at higher risk of FNAIT, which is on track for the second half of 2024," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Last month, we were particularly pleased to announce our collaboration with Johnson & Johnson, marking a significant step forward in our mission to eliminate FNAIT and its devastating consequences. Together with Johnson & Johnson, we look forward to further driving awareness of FNAIT, emphasizing the importance of screening for FNAIT risk, and advancing our complementary therapeutic approaches, which aim to ensure all pregnant women at risk of FNAIT have a potential treatment option regardless of their alloimmunization status."

Dr. Uden continued, "In the near-term, we look forward to sharing initial data from an epidemiologic analysis investigating the genetic markers of FNAIT risk in a racially and ethnically diverse population beyond the Caucasian population, where FNAIT risk has been better established in published literature. This analysis will more accurately inform the number of pregnant women at higher risk for FNAIT annually. We expect that these data combined with data from our ongoing FNAIT natural history study will further emphasize the need for a preventative therapeutic and identify a market opportunity for RLYB212 that is larger than our current estimates."

Recent Business Highlights and Upcoming Milestones:

Corporate Updates

- In April 2024, Rallybio announced a collaboration with Momenta Pharmaceuticals, Inc., a Johnson & Johnson Company, to advance complementary therapeutic solutions for pregnant women at risk of fetal and neonatal alloimmune thrombocytopenia (FNAIT). Rallybio received an equity investment of $6.6 million from Johnson & Johnson Innovation – JJDC, Inc.

- In February 2024, Rallybio announced a prioritization of its portfolio and a 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 FNAIT, and RLYB116, a once-weekly, low volume subcutaneously injected inhibitor of complement component 5 (C5) in development for patients with complement-mediated diseases.

RLYB212 Program

- Rallybio is on track to initiate a Phase 2 trial in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT in the second half of 2024. The primary objectives of this trial are to assess the pharmacokinetics and safety of subcutaneously administered RLYB212 in pregnant women. Secondary objectives include assessments of pregnancy and neonatal outcomes, and the occurrence of emergent HPA-1a alloimmunization. Administration of RLYB212 will be initiated by Gestational Week 16 and continue every 4 weeks through parturition.

- Screening in the Company's FNAIT natural history study is ongoing. This study is designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population. As of May 1, 2024, Rallybio has screened approximately 10,000 pregnant women. The FNAIT natural history study is designed to run in parallel with the Phase 2 study and to continue through to initiation of the planned Phase 3 trial to enable seamless transition of participating sites into the registration trial.

- To better understand the frequency of HPA-1a-negative, HLA-DRB3*01:01-positive status in a broad and diverse population, Rallybio partnered with HealthLumen, a leader in epidemiological modeling of rare genetic diseases, to conduct an epidemiologic analysis utilizing information from large genomic datasets. Rallybio expects data from this analysis to be disclosed in mid-2024.

- Several presentations and publications are expected in the second half of 2024, including additional data from the Phase 1b proof-of-concept study and an integrated summary of clinical and nonclinical data supporting the RLYB212 Phase 2 dose.

RLYB116 Program

- RLYB116 manufacturing work continues and is on track to complete in the second half of 2024. Furthermore, additional biomarker development work is underway to further evaluate results of the Phase 1 multiple ascending dose (MAD) study, which was completed in the fourth quarter of 2023. Rallybio expects to provide an update on this analysis and future development plans for RLYB116 in the second half of 2024.

Preclinical Programs

Rallybio continues to believe that its preclinical programs have the potential to address significant existing unmet needs for patients and caregivers and bring meaningful value to stakeholders. Given Rallybio's focus of current capital and resources on its clinical-stage assets, primarily RLYB212, the Company is seeking alternative options to further advance its preclinical programs, including partnerships and other forms of non-dilutive financing.

- **RLYB332:** In the first quarter of 2024, Rallybio completed nonclinical studies that demonstrated favorable tolerability, dose-dependent pharmacokinetics, and sustained pharmacodynamic effects with RLYB332, a long-acting version of the RLYB331 anti-Matriptase-2 antibody. These findings support the continued development of RLYB332 as a potentially best-in-class therapeutic for treating diseases of iron overload. Presentation of this data is expected in the second half of 2024.

- **RLYB114, EyePoint Collaboration:** EyePoint has demonstrated feasibility for sustained delivery of Rallybio’s inhibitor of C5 using EyePoint’s proprietary intraocular drug delivery technology, and optimization work is ongoing.

First Quarter 2024 Financial Results

- **Research & Development (R&D) Expenses:** R&D expenses were $12.9 million for the first quarter of 2024, compared to $11.2 million for the same period in 2023. The increase in R&D expense was primarily due to an increase in payroll and personnel-related costs, largely related to severance costs incurred in connection with the workforce reduction, effective March 6, 2024. The increase was partially offset by a decrease in costs related to the development of RLYB212.

- **General & Administrative (G&A) Expenses:** G&A expenses were $6.9 million for the first quarter of 2024, compared to $7.2 million for the same period in 2023. The decrease in G&A expense was primarily related to decreases in other general and administrative related expenses and director and officer insurance premiums. This decrease was partially offset by an increase in payroll and personnel-related costs, primarily related to severance costs incurred in connection with the workforce reduction, effective March 6, 2024.

- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net loss of $19.0 million, or $0.47 per common share, for the first quarter of 2024. This compares to a net loss of $17.3 million, or $0.43 per common share, for the first quarter of 2023.

- **Cash Position:** As of March 31, 2024, cash, cash equivalents, and marketable securities were $94.2 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, the timing of the availability of data from our clinical studies, our expectations regarding the usefulness of data from our clinical studies, our expectations regarding driving awareness of FNAIT through the Johnson & Johnson collaboration, our ability to more accurately identify the number of pregnant women at higher risk of FNAIT based on the results of the genomic analysis, our estimates of the market opportunity for RLYB212, the timing of publications relating to FNAIT and RLYB212, the timing of completion of the RLYB116 biomarker work, 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, our estimates of our capital requirements and the sufficiency thereof, 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 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 Annual Report on Form 10-K for the period ended December 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 MARCH 31, 2024	2023
Operating expenses:		
Research and development	$ 12,936	$ 11,202
General and administrative	6,851	7,172
Total operating expenses	19,787	18,374
Loss from operations	(19,787)	(18,374)
Other income:		
Interest income	1,276	1,546
Other income	167	73
Total other income, net	1,443	1,619
Loss before equity in losses of joint venture	(18,344)	(16,755)
Loss on investment in joint venture	685	563
Net loss	$ (19,029)	$ (17,318)
Net loss per common share, basic and diluted	$ (0.47)	$ (0.43)
Weighted-average common shares outstanding, basic and diluted	40,773,615	40,248,893
Other comprehensive (loss) gain:		
Net unrealized (loss) gain on marketable securities	(86)	153
Other comprehensive (loss) gain	(86)	153
Comprehensive loss	$ (19,115)	$ (17,165)

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	MARCH 31, 2024	DECEMBER 31, 2023
Cash, cash equivalents and marketable securities	$ 94,175	$ 109,929
Total assets	99,359	115,620
Total liabilities	10,202	9,436
Total stockholders' equity	89,157	106,184

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