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): February 6, 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 February 6, 2024, Rallybio Corporation (Rallybio) issued a press release (the Press Release) that contained an estimate of its cash, cash equivalents and marketable securities as of December 31, 2023. This information is preliminary and unaudited.

A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 2.05 Costs Associated with Exit or Disposal Activities.

On February 6, 2024, Rallybio announced the prioritization of its portfolio and a workforce reduction to focus resources on its Phase 2-ready clinical stage programs, RLYB212 and RLYB116.

As part of this effort, Rallybio will eliminate approximately 45% of its current positions. As a result of these actions, Rallybio expects to incur charges of approximately $3.3 million, excluding share-based compensation expense. The charges related to the workforce reduction are cash-based expenditures related primarily to one-time severance and benefit payments. Rallybio expects to recognize substantially all charges related to the workforce reduction in the quarter ending March 31, 2024. These estimates are subject to assumptions and actual results may differ.

In connection with the announcement, Rallybio issued the Press Release, a copy of which is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Forward-Looking Statements

This Current Report 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 Current Report 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 include, but are not limited to, estimated expenses to be incurred in connection with Rallybio's planned workforce reduction and other statements related to the planned workforce reduction. The forward-looking statements in this Current Report 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 Current Report and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to 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, Rallybio is 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on February 6, 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: February 6, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Exhibit 99.1

Rallybio Announces Portfolio Prioritization and Provides Corporate Update

— Prioritization of Phase 2-ready clinical-stage programs: RLYB212 for the prevention of FNAIT and RLYB116, a C5 inhibitor for the treatment of patients with complement-mediated diseases —

— Anticipated cost savings, including a 45% workforce reduction, extends cash runway into mid-2026 –

NEW HAVEN, Conn., February 6, 2024 (BUSINESS WIRE) – Rallybio Corporation (Nasdaq: RLYB) today announced the prioritization of its portfolio and a 45% workforce reduction to focus resources on its Phase 2-ready clinical stage programs, RLYB212 and RLYB116. RLYB212 is a novel human monoclonal anti-HPA-1a antibody in development for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT), and RLYB116 is 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 expects to extend its cash runway into mid-2026.

"Following a thorough review of our business, we have made the decision to prioritize our portfolio. We believe that these difficult but necessary decisions to streamline our operations and align resources are critical to extend our cash runway, support the advancement of our two clinical-stage programs, and put us on a path toward long-term success," said Stephen Uden, M.D. Chief Executive Officer of Rallybio.

“I would like to personally thank our departing employees for their countless contributions and tireless commitment to our mission,” Dr. Uden continued. “It is incredibly difficult to part ways with these talented members of the Rallybio team who have demonstrated such dedication to bringing transformative therapies to patients in need.”

Key Elements of Portfolio Prioritization and Corporate Update

Prioritization of Clinical-Stage Programs

RLYB212

- The Company plans to provide an update on Phase 2 discussions for RLYB212 with the European Medicines Agency (EMA) in the first half of 2024.
- Rallybio continues to expect to initiate a Phase 2 dose confirmation study for RLYB212 in pregnant women at higher risk of FNAIT in the second half of 2024.
- The Company continues to screen mothers 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. Rallybio expects to provide an update on screening numbers in its full-year earnings release in March 2024.

RLYB116

- Manufacturing work announced in December 2023 is progressing, and Rallybio is encouraged by data indicating the potential to achieve improved tolerability at higher doses of RLYB116.
- While the exposure levels 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 the ongoing 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.
- Rallybio continues to expect to complete this manufacturing work and provide an update on the development plan for RLYB116 in the second half of 2024.

Preclinical Program Update

The Company 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. 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.
- **RLYB114, EyePoint Collaboration:** The evaluation of Rallybio's C5 inhibitor using EyePoint's proprietary technology for sustained intraocular drug delivery is ongoing. An update is expected in the first half of 2024.

Workforce Reduction
The Company will implement a 45% workforce reduction, representing 19 positions, which 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 and excluding share-based compensation expense.

Based on the above actions, Rallybio's cash, cash equivalents and marketable securities of approximately $109.9 million (unaudited) as of December 31, 2023, are now expected to fund its revised operating plan into mid-2026.

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, 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 studies, and complete such clinical studies 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 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.

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

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

Media
Lauren Cohen
Mission North
410-570-2497
lcohen@missionnorth.com