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): August 08, 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 August 8, 2024, Rallybio Corporation issued a press release announcing its financial results for the quarter ended June 30, 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 August 8, 2024 regarding financial results for the fiscal quarter ended June 30, 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: August 8, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Rallybio Reports Second 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 4Q 2024 –

– $88.6 Million in Cash, Cash Equivalents, and Marketable Securities as of June 30, 2024 Provides Runway into Mid-2026 –

NEW HAVEN, Conn., August 8, 2024 -- Rallybio Corporation (Nasdaq: RLYB), a clinical-stage biotechnology company translating scientific advances into transformative therapies for patients with devastating rare diseases, today reported second quarter financial results for the period ended June 30, 2024, and provided an update on recent company developments.

“We are working expeditiously towards the initiation of our Phase 2 dose confirmation trial for RLYB212 in pregnant women at higher risk of fetal and neonatal alloimmune thrombocytopenia (FNAIT), which is on track for the fourth quarter of 2024," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Recent data from our large-scale genomic analysis of FNAIT risk across a broad population of diverse ancestries provides the first clear evidence that the proportion of pregnant women at higher risk for FNAIT each year has been significantly underestimated, giving us even greater urgency to bring RLYB212 to this underserved population that comprises a market opportunity of more than $1.6 billion. We look forward to providing updates as we continue to advance our RLYB212 program with a team of highly dedicated investigators who share our mission to prevent this devastating disease."

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 FNAIT. Rallybio received an equity investment of $6.6 million, before deducting offering expenses, from Johnson & Johnson Innovation – JJDC, Inc. In addition, Rallybio received an upfront payment of $0.5 million related to the collaboration and license agreement with Johnson & Johnson.

RLYB212 Program

- Rallybio remains on track to initiate a Phase 2 trial in pregnant women at higher risk for HPA-1a alloimmunization and FNAIT in the fourth quarter 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.

- The Company reported top line results from an epidemiological analysis that provided the first clear and robust evidence quantifying the proportion of women of non-Caucasian ancestries that carry the genetic markers for higher FNAIT risk (HPA-1a negative, HLA-DRB3*01:01 positive). These data indicate that the proportion of pregnant women at higher risk for FNAIT each year has been significantly underestimated. Specifically, in key geographies of North America and major European countries, it is estimated that more than 30,000 pregnancies each year are at higher risk for FNAIT, representing a 40% increase from prior estimates. Full data from the epidemiological analysis are expected to be presented at a scientific conference in the fourth quarter of 2024.

- Screening in the Company's FNAIT natural history study is ongoing, with more than 12,000 pregnant women screened as of August 1, 2024. In the third quarter of 2024, Rallybio will begin to transition European sites from the natural history study to the Phase 2 trial, where sites will continue to collect natural history data in women who are not administered RLYB212. North American sites will continue to screen pregnant women in the natural history study which will be progressed in parallel with the Phase 2 trial. The totality of natural history data from both studies is designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population that can serve as a control arm for the planned Phase 3 trial.

- Several presentations and publications are expected in the second half of 2024, including additional data from the Phase 1b proof-of-concept study and the rationale and modeling that support the RLYB212 Phase 2 dose regimen.

RLYB116 Program

- RLYB116 manufacturing work is progressing and is on track to be completed in the third quarter of 2024. Drug substance characterization data indicates that Rallybio's efforts to enhance the manufacturing process have been successful.

- Additional complement biomarker analysis for RLYB116 is ongoing, with full data expected in the fourth quarter of 2024. This work expands our understanding of the results of the Phase 1 multiple ascending dose (MAD) study, which was completed in the fourth quarter of 2023. Based on these analyses, Rallybio believes that there is an opportunity to pursue indications beyond generalized myasthenia gravis (gMG), including paroxysmal nocturnal hemoglobinuria (PNH) and antiphospholipid syndrome (APS), at doses tested in the Phase 1 MAD study.

- The Company will provide an update on future plans for RLYB116 later this year.

Preclinical Programs

In accordance with its 2024 operating plan, Rallybio is advancing its preclinical programs to important 2024 milestones. Beyond achievement of these milestones, Rallybio is seeking alternative options to further advance its preclinical programs, including partnerships and other forms of non-dilutive financing.

- **RLYB332:** Presentation of nonclinical data demonstrating favorable tolerability, dose-dependent pharmacokinetics, and sustained pharmacodynamic effects with RLYB332, a long-acting version of the RLYB331 anti-matriptase-2 antibody, is expected in the fourth quarter of 2024.

- **ENPP1 Inhibitor, Exscientia Partnership:** Rallybio and Exscientia expect to achieve development candidate nomination of a small molecule inhibitor of ENPP1 for the treatment of patients with hypophosphatasia (HPP) in the fourth quarter of 2024. In addition, data from an early lead compound in a nonclinical model of HPP will be presented at the American Society for Bone and Mineral Research (ASBMR) meeting which is being held from September 27 – 30, 2024 in Toronto, ON, Canada.

Second Quarter 2024 Financial Results

- **Revenue:** Revenue was $0.3 million for the second quarter of 2024, compared to no revenue in the same period in 2023. The increase was related to Rallybio's entrance into the collaboration and license agreement with Johnson & Johnson in the second quarter of 2024 and the recognition of revenue related to the collaboration's performance obligations.

- **Research & Development (R&D) Expenses:** R&D expenses were $12.9 million for the second quarter of 2024, compared to $13.1 million for the same period in 2023. The decrease in R&D expense was primarily due to a decrease in payroll and personnel-related costs, largely offset by an increase in development costs related to RLYB212 and RLYB116.

- **General & Administrative (G&A) Expenses:** G&A expenses were $4.4 million for the second quarter of 2024, compared to $7.0 million for the same period in 2023. The decrease in G&A expense was primarily related to lower payroll and personnel-related costs, largely related to the workforce reduction and lower ongoing headcount in 2024 as compared to 2023, and reductions in consulting fees, director and officer insurance premiums, professional fees and other G&A expenses.

- **Net Loss and Net Loss Per Common Share:** Rallybio reported a net loss of $16.2 million, or $0.37 per common share, for the second quarter of 2024. This compares to a net loss of $18.6 million, or $0.46 per common share, for the second quarter of 2023.

- **Cash Position:** As of June 30, 2024, cash, cash equivalents, and marketable securities were $88.6 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 trial for RLYB212, whether the results of the FNAIT natural history study and the planned Phase 2 dose confirmation trial will be sufficient to support design and implementation of a Phase 3 registrational study for RLYB212, whether the manufacturing work for RLYB116 will result in improved tolerability, if and when tested in a clinical trial, 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 epidemiological analysis, our estimates of the market opportunity for RLYB212, the timing of publications relating to FNAIT and RLYB212, whether our conclusions from the RLYB116 biomarker work will be informative, the timing of achieving milestones in 2024 for our preclinical programs, the timing of publications, 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 Quarterly Report on Form 10-Q for the period ended March 31, 2024, 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 JUNE 30, 2024	FOR THE THREE MONTHS ENDED JUNE 30, 2023	FOR THE SIX MONTHS ENDED JUNE 30, 2024	FOR THE SIX MONTHS ENDED JUNE 30, 2023
Revenue:				
Collaboration and license revenue	$ 299	$ —	$ 299	$ —
Total revenue	299	—	299	—
Operating expenses:				
Research and development	12,946	13,130	25,882	24,332
General and administrative	4,388	6,953	11,239	14,125
Total operating expenses	17,334	20,083	37,121	38,457
Loss from operations	(17,035)	(20,083)	(36,822)	(38,457)
Other income:				
Interest income	1,143	1,608	2,419	3,154
Other income	143	62	310	135
Total other income, net	1,286	1,670	2,729	3,289
Loss before equity in losses of joint venture	(15,749)	(18,413)	(34,093)	(35,168)
Loss on investment in joint venture	487	217	1,172	780
Net loss	$ (16,236)	$ (18,630)	$ (35,265)	$ (35,948)
Net loss per common share, basic and diluted	$ (0.37)	$ (0.46)	$ (0.83)	$ (0.89)
Weighted-average common shares outstanding, basic and diluted	44,128,059	40,363,902	42,450,837	40,306,715
Other comprehensive loss:				
Net unrealized loss on marketable securities	—	(211)	(86)	(58)
Other comprehensive loss	—	(211)	(86)	(58)
Comprehensive loss	$ (16,236)	$ (18,841)	$ (35,351)	$ (36,006)

Condensed Consolidated Balance Sheets
(Unaudited)

(in thousands)	JUNE 30, 2024	DECEMBER 31, 2023
Cash, cash equivalents and marketable securities	$ 88,614	$ 109,929
Total assets	92,431	115,620
Total liabilities	12,414	9,436
Total stockholders' equity	80,017	106,184

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