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 8, 2022

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** **(Address of Principal Executive Offices)**	**06510** **(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, 2022, Rallybio Corporation issued a press release announcing its financial results for the quarter ended June 30, 2022. 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, 2022 regarding financial results for the quarter ended June 30, 2022
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, 2022

By: /s/ Jeffrey M. Fryer
Jeffrey M. Fryer, CPA
Chief Financial Officer and Treasurer

Exhibit 99.1

Rallybio Reports Second Quarter 2022 Financial Results

-- Emerging data from Phase 1b study of RLYB212 shows rapid and complete elimination of transfused HPA-1a positive platelets --
-- Phase 1 study of RLYB116 ongoing; initial single dose safety, PK, and PD data expected for the 30 mg dose in the 4Q 2022--

NEW HAVEN, Conn. August 8, 2022-- 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 second quarter ended June 30, 2022 and provided an update on recent program and corporate developments.

“We continue to progress our pipeline toward planned upcoming milestones. We are pleased to see that the emerging clinical data from our ongoing Phase 1b proof-of-concept study of subcutaneous RLYB212 shows rapid and complete elimination of transfused HPA-1a positive platelets. These data are consistent with the projected effective therapeutic target concentrations of RLYB212 required to prevent maternal alloimmunization and FNAIT,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio.

“With these data, in order to further characterize the advantages associated with subcutaneous dosing, we are amending the protocol to expand the dose range of RLYB212. This amendment will provide a broader range of PK/PD data to inform decision-making as we seek to select dosing for a future registrational study. We expect to discuss the preliminary platelet elimination data by the end of the third quarter of 2022 as planned and to release PoC data in the first quarter of 2023.”

Dr. Mackay continued, “Our Phase 1 study for subcutaneous RLYB116, which is in development for the treatment of patients with complement-related diseases, remains on track with initial data expected for the 30 mg dose in the fourth quarter of 2022. We are also conducting IND-enabling activities for RLYB331, which we believe could treat multiple severe, non-malignant hematological disorders. We believe that our existing capital will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2024.”

Recent Business Highlights and Upcoming Milestones:

Maternal Fetal Blood Disorders
Rallybio announced in May 2022 that it had initiated the Phase 1b proof-of-concept study to establish the ability of RLYB212 to rapidly eliminate transfused HPA-1a positive platelets from the circulation of HPA-1a negative healthy subjects.

In order to further characterize the absorption and concentration-effect relationship of RLYB212 to platelet elimination, the Company is amending the protocol to expand the dose range . RLYB212 has been well tolerated, and no serious adverse events have been reported to date. Rallybio expects to discuss the preliminary platelet elimination data by the end of the third quarter of 2022 and to release PoC data in the first quarter of 2023.

Rallybio continues to advance the FNAIT natural history alloimmunization 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 that the data from this study will contribute to a control dataset for a future single armed registration trial for RLYB212.

Rallybio announced today the publication of a manuscript titled “Prophylactic administration of HPA-1a-specific antibodies prevents fetal/neonatal alloimmune thrombocytopenia in mice.” This paper, published in the peer-reviewed journal, *Blood*, evaluates the ability of RLYB212 and RLYB211 to prevent alloimmunization in an authentic murine model of FNAIT. Findings from these studies demonstrate that low doses of RLYB212 and RLYB211 effected both the rapid and complete elimination of HPA-1a-positive platelets from circulation and prevention of HPA-1a alloimmunization. These preclinical data establish both the potential and threshold exposure targets for prophylactic treatment with RLYB212 and RLYB211 for the prevention of FNAIT in humans.

Complement Dysregulation
Rallybio initiated a Phase 1 study in healthy participants of RLYB116, a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with complement-related diseases in the first quarter of 2022. The single-blind, placebo-controlled dose escalation study is designed to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of single dose RLYB116 in healthy volunteers and remains on track, with initial data for the 30 mg dose expected in the fourth quarter of 2022.

Rallybio continues to advance development of RLYB114 for intravitreal administration for the treatment of ophthalmic disorders.

Metabolic Disorders
Rallybio, together with its partner Exscientia, continues to work toward the selection of a development candidate to advance into the clinic targeting ENPP1 for the treatment of patients with hypophosphatasia (HPP). Investigational new drug (IND)-enabling studies are expected to commence in the second half of 2022.

Hematological Disorders
Rallybio continues to conduct IND-enabling activities for RLYB331, a preclinical potentially first-in-class therapeutic monoclonal antibody that inhibits Matriptase-2 (MTP-2), to support transition of the asset into clinical development. RLYB331 has the potential to treat multiple disorders characterized by severe anemias and ineffective erythropoiesis with iron overload including beta thalassemia and a subset of myelodysplastic syndromes.

Rallybio announced in May 2022 that it obtained worldwide exclusive rights to RLYB331, previously known as KY1066, from Sanofi.

Corporate

In August 2022, Rallybio announced the appointment of Wendy Chung, M.D., Ph.D., to its Board of Directors. Dr. Chung is a board certified clinical and molecular geneticist with more than 20 years of experience in human genetic research. She is currently the Kennedy Family Professor of Pediatrics and Medicine at Columbia University Irving Medical Center and the Director of Precision Medicine Resource for the Irving Institute for Translational Research at Columbia University.

Rallybio announced in June 2022 that Jeffrey Fryer, CPA, will retire from his position as Chief Financial Officer (CFO). Mr. Fryer will continue to serve as Rallybio's CFO until a new CFO has been appointed and will retire from the Company following a transition period. Rallybio has initiated an external search to identify its next CFO.

Second Quarter 2022 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $10.1 million for the second quarter of 2022, compared to $6.8 million for the same period in 2021. The increase in R&D expenses was primarily due the result of a $3.1 million increase in asset acquisition IPR&D expense related to the second quarter 2022 acquisition of the worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, and increases in R&D payroll and personnel-related expenses. These increases were partially offset by a decrease in clinical manufacturing expenses of RLYB212 and RLYB116 and a decrease in costs related to the development of RLYB211 as we continue to develop our lead product candidate, RLYB212.
- **General & Administrative (G&A) Expenses:** G&A expenses were $7.5 million for the second quarter of 2022, compared to $3.7 million for the same period in 2021. The increase in G&A expenses was primarily due to an increase in payroll and personnel-related costs due to an increase in general and administrative related headcount, including an increase of $1.4 million in share-based compensation, an increase in other professional fees, costs associated with operating as a public company and an increase in business development expenses.
- **Net Loss and Net Loss Per Common Share:** Net loss was $17.6 million for the second quarter of 2022, or net loss per common share of $0.57 compared to a net loss of $11.1 million, or net loss per common share of $0.49 for the second quarter of 2021.
- **Cash Position:** As of June 30, 2022, cash, cash equivalents, and marketable securities were $147.4 million.

About Rallybio

Rallybio is a clinical-stage biotechnology company committed to identifying and accelerating the development of life-transforming therapies for patients with severe and rare diseases. Since its launch in January 2018, Rallybio has built a portfolio of promising product candidates, which are now in development to address rare diseases in the areas of hematology, immuno-inflammation, maternal fetal health, and metabolic disorders. The Company's mission is being advanced by a team of highly experienced biopharma industry leaders with extensive research, development, and rare disease expertise. 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**.

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. 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, initiation and timing of our planned studies for RLYB212 and RLYB116, and the timing of the availability of data from such studies, the initiation and timing of our pre-IND enabling studies for our ENPP1 inhibitor, and the timing of the availability of data from such studies, and the therapeutic effects of RLYB331. 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 integrate RLYB331 into our pipeline, 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, 2021, 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, 2022	FOR THE THREE MONTHS ENDED JUNE 30, 2021	FOR THE SIX MONTHS ENDED JUNE 30, 2022	FOR THE SIX MONTHS ENDED JUNE 30, 2021
Operating expenses:				
Research and development	$ 10,138	$ 6,818	$ 17,786	$ 15,855
General and administrative	7,477	3,712	14,147	7,499
Total operating expenses	17,615	10,530	31,933	23,354
Loss from operations	(17,615)	(10,530)	(31,933)	(23,354)
Other income (expenses):				
Interest income	270	13	367	30
Interest expense	—	—	—	(10)
Other income (expense)	100	(142)	213	(118)
Total other income (expense), net	370	(129)	580	(98)
Loss from continuing operations	(17,245)	(10,659)	(31,353)	(23,452)
Loss on investment in joint venture	338	468	728	950
Net loss	$ (17,583)	$ (11,127)	$ (32,081)	$ (24,402)
Net loss per common share, basic and diluted	$ (0.57)	$ (0.49)	$ (1.05)	$ (1.09)
Weighted average common shares outstanding, basic and diluted	30,588,931	22,559,706	30,453,913	22,309,203
Other comprehensive loss:				
Net unrealized loss on marketable securities	249	—	371	—
Other comprehensive loss	(249)	—	(371)	—
Comprehensive loss	$ (17,832)	$ (11,127)	$ (32,452)	$ (24,402)

Condensed Consolidated Balance Sheets (Unaudited)

(in thousands)	JUNE 30, 2022	DECEMBER 31, 2021
Cash, cash equivalents, and marketable securities	$ 147,368	$ 175,334
Total assets	155,607	182,185
Total liabilities	7,756	6,583
Total stockholders' equity	147,851	175,602

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