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 15, 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**	**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 15, 2022, Rallybio Corporation issued a press release announcing its financial results for the year and quarter ended December 31, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in 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 15, 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: March 15, 2022

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

Exhibit 99.1

Rallybio Reports Fourth Quarter and Full Year 2021 Financial Results

-- Phase 1b proof-of-concept study for RLYB212 in development for the prevention of FNAIT on track to commence in 2Q 2022; initial data expected in 3Q 2022 --

-- First healthy volunteers dosed in Phase 1 study of RLYB116; single dose safety, PK, and PD data expected in 2H 2022 --

-- Advancing preclinical development of ENPP1 inhibitor; IND-enabling studies expected to initiate in 2H 2022 --

NEW HAVEN, Conn. Mar. 15, 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 fourth quarter and full year ended December 31, 2021 and provided an update on recent corporate developments.

“Following our successful initial public offering in August 2021, we continue to advance our broad portfolio of product candidates, each with the potential to significantly transform the lives of patients with severe and rare disorders. We look forward to a number of upcoming milestones in the year ahead,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. “In January we announced that first subjects had been dosed in the Phase 1 study of RLYB212, our lead product candidate for the prevention of fetal and neonatal alloimmune thrombocytopenia, also referred to as FNAIT, which will evaluate safety and pharmacokinetics. We expect to initiate a subsequent Phase 1b proof-of-concept study in the second quarter and to announce initial data in the third quarter of 2022.”

Dr. Mackay continued, “Beyond our FNAIT program, we continue to advance our complement dysregulation program. We are pleased to have recently initiated a Phase 1 healthy volunteer study of RLYB116, our C5 inhibitor in development for the treatment of patients with PNH and gMG, and currently expect data in the second half of 2022. Lastly, our team continues to evaluate global business development opportunities as we seek to expand our current portfolio with differentiating assets that have the potential to deliver transformative outcomes to patients.”

Rallybio’s current pipeline is focused on addressing diseases in the areas of hematology, immune-inflammation, maternal fetal health, and metabolic disorders.

Recent Business Highlights and Upcoming Milestones:

Maternal Fetal Blood Disorders

In January 2022, Rallybio announced that the first subjects have been dosed in its Phase 1 study of RLYB212, a novel human monoclonal anti-HPA-1a antibody in development for the prevention of FNAIT (fetal and neonatal alloimmune thrombocytopenia). The single-blind, placebo-controlled Phase 1 study is evaluating the safety and pharmacokinetics (PK) of single and repeat subcutaneous doses of RLYB212 in HPA-1a negative healthy subjects.

Rallybio expects to initiate a subsequent 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 the second quarter of 2022. Initial data from this study are expected in the third quarter of 2022.

In December 2021, Rallybio announced additional data from its ongoing Phase 1 / 2 study of RLYB211, a plasma-derived polyclonal anti-HPA-1a antibody also being evaluated for the prevention of FNAIT. Administration of RLYB211 was observed to accelerate the elimination of HPA-1a positive platelets through seven days following administration compared to placebo. Consistent with previously reported data in an abstract submitted to the International Society on Thrombosis and Haemostasis Congress in July 2021, these results showed acceptable safety and tolerability with no serious adverse events. Collectively, the RLYB211 clinical data demonstrate the sustained treatment capacity of anti-HPA-1a antibodies to cause rapid and complete elimination of mismatched platelets from the circulation of HPA-1a negative healthy subjects, and support Rallybio's development of RLYB212, which has the same mechanism of action as RLYB211.

Complement Dysregulation

Rallybio announced today that it has initiated a Phase 1 study 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. The single-blind, placebo-controlled dose escalation study is designed to evaluate the safety, PK, and pharmacodynamics of single dose RLYB116 in healthy volunteers. Initial data are expected in the second half of 2022.

Metabolic Disorders

Rallybio, together with its partner Exscientia, is working to select 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.

Fourth Quarter and Full Year 2021 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $6.1 million for the fourth quarter of 2021, compared to $7.5 million for the same period in 2020. R&D expenses were $26.9 million for the year ended December 31, 2021 compared to $17.6 million for the year ended December 31, 2020. R&D expenses for the year ended December 31, 2021 increased primarily related to an increase direct spend on RLYB212 and RLYB114 in addition to increased R&D related headcount costs as compared to the prior year.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.2 million for the fourth quarter of 2021, compared to $2.6 million for the same period in 2020. G&A expenses were $18.7 million for the year ended December 31, 2021 compared to $7.7 million for the year ended December 31, 2020. The increase in general and administrative expenses for both the fourth quarter and full year was primarily due to additional G&A related headcount, increased non-cash share-based compensation expense, and an increase in other professional fees, costs associated with operating as a public company and an increase in business development supporting expenses as compared to the prior year.

- **Net Loss and Net Loss Per Common Share:** Net loss was $12.4 million for the fourth quarter of 2021, or net loss per common share of $0.42 compared to a net loss of $10.5 million, or net loss per common share of $0.47 for the fourth quarter of 2020. Net loss was $47.0 million, or net loss per share of $1.84, for the year ended December 31, 2021 compared to $26.4 million, or net loss per share of $1.52, for the year ended December 31, 2020.
- **Cash Position:** As of December 31, 2021, cash and cash equivalents were $175.3 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. 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, 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, 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.

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RALLYBIO CORPORATION
Consolidated Statements of Operations and Comprehensive Loss (unaudited) [1]

(in thousands, except share and per share amounts)	THREE MONTHS ENDED DECEMBER 31, 2021	THREE MONTHS ENDED DECEMBER 31, 2020	YEAR ENDED DECEMBER 31, 2021	YEAR ENDED DECEMBER 31, 2020
Operating expenses:				
Research and development	$ 6,094	$ 7,495	$ 26,909	$ 17,630
General and administrative	6,219	2,592	18,739	7,673
Total operating expenses	12,313	10,087	45,648	25,303
Loss from operations	(12,313)	(10,087)	(45,648)	(25,303)
Other income (expenses):				
Interest income	12	27	54	171
Interest expense	-	(12)	(10)	(49)
Other income	109	68	96	241
Total other income, net	121	83	140	363
Loss before income taxes	(12,192)	(10,004)	(45,508)	(24,940)
Income tax benefit	—	1	—	(15)
Loss on investment in joint venture	223	513	1,505	1,522
Net loss and comprehensive loss	$ (12,415)	$ (10,518)	$ (47,013)	$ (26,447)
Net loss per common share, basic and diluted	$ (0.42)	$ (0.47)	$ (1.84)	$ (1.52)
Weighted average common shares outstanding, basic and diluted	29,789,974	22,226,097	25,519,114	17,388,239

RALLYBIO CORPORATION
Consolidated Balance Sheets (unaudited)[1]

(in thousands)	DECEMBER 31, 2021	DECEMBER 31, 2020
Cash and cash equivalents	$ 175,334	$ 140,233
Total assets	182,185	141,858
Total liabilities	6,583	5,855
Total stockholders' equity	175,602	136,003

(1) Prior to the IPO, Rallybio Corporation was a 100% owned subsidiary of Rallybio Holdings, LLC ("Rallybio Holdings"), a Delaware limited liability company which was incorporated in Delaware on March 22, 2018 and Rallybio Holdings held 100% of the outstanding membership units in five wholly-owned subsidiaries; Rallybio, LLC, Rallybio IPA, LLC, Rallybio IPB, LLC, Rallybio IPD LLC, and IPC Research, LLC prior to the IPO and it's liquidation. On June 30, 2021, Rallybio Holdings completed a series of transactions pursuant to which (i) Rallybio IPD, LLC, a direct subsidiary of Rallybio Holdings that was formed in Delaware in May 2020, was converted from a Delaware limited liability company to a Delaware corporation and changed its name to Rallybio Corporation, and (ii) four direct subsidiaries of Rallybio Corporation, each a Delaware limited liability company (collectively the "Merger Subs"), each consummated a separate merger with one of Rallybio Holdings direct subsidiaries, other than Rallybio IPD, LLC (collectively the "Asset Subsidiaries"), with the Asset Subsidiaries surviving the mergers and Rallybio Holdings receiving common stock of Rallybio Corporation in exchange for its interest in each Asset Subsidiary, which resulted in the Asset Subsidiaries becoming subsidiaries of Rallybio Corporation and the Rallybio Corporation becoming the only direct subsidiary of Rallybio Holdings. On July 28, 2021, immediately prior to the completion of the IPO, Rallybio Holdings liquidated and distributed 100% of the capital stock of Rallybio Corporation, consisting solely of common stock, to the unitholders of Rallybio Holdings. The liquidation of Rallybio Holdings and distribution of the capital stock of Rallybio Corporation to the unitholders of Rallybio Holdings is referred to as the “Liquidation” and these other transactions are collectively referred to as the “Reorganization.” As a result of the Liquidation, the holders of units in

Rallybio Holdings collectively were issued an aggregate of 24,999,970 shares of common stock of the Company prior to the completion of the IPO.

The Reorganization and subsequent Liquidation resulted in a change in reporting entity as described in ASC 250. In accordance with the guidance applicable to these circumstances, the equity structure has been adjusted in all comparative periods up to the Liquidation to reflect the number of shares of Rallybio Corporation’s common stock, issued to Rallybio Holdings unitholders' in connection with the Liquidation. As such, historical Rallybio Holdings convertible redeemable preferred units, common units, and incentive units have been retroactively adjusted to shares and earnings per share in accordance with the ratio of common shares received by each membership unit class. Rallybio Holdings' convertible redeemable preferred units previously classified as mezzanine equity have been retroactively adjusted in these financial statements, converted into common stock, and reclassified to permanent as a result of the retrospective application of the Liquidation and change in reporting entity.