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): September 09, 2021

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 September 9, 2021, Rallybio Corporation issued a press release announcing its financial results for the quarter ended June 30, 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 September 9, 2021
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: September 9, 2021

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

Exhibit 99.1

Rallybio Corporation Reports Second Quarter 2021 Financial Results and Recent Business Highlights

– Completed initial public offering for $92.7 million of gross proceeds–

– Clinical proof-of-concept data for RLYB211 for the prevention of FNAIT was presented at the ISTH Virtual Congress; Additional Phase 1/2 data expected in 4Q 2021–

– On-track to initiate Phase 1 studies of RLYB212, in development for the prevention of FNAIT, and RLYB116, in development for the treatment of patients with PNH and gMG, in 1Q 2022–

New Haven, Conn. -- September 9, 2021 -- 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 its financial results for the second quarter ended June 30, 2021 and provided an update on recent corporate developments.

“Since our founding in 2018, Rallybio has made consistent progress towards achieving our mission to truly transform the lives of patients with severe and rare diseases. With a tremendous team, we have now built a diversified portfolio of five programs, and we continue to work expeditiously to advance our pipeline,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. “Following the closing of our initial public offering in early August, we are operating from a position of financial strength, and we are poised to build on this momentum in the months ahead, with additional Phase 1/2 data for RLYB211 expected before year end, and the initiation of Phase 1 studies of RLYB212 and RLYB116 both planned for the first quarter of 2022.”

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

Recent 2021 Business Highlights:

- In July 2021, Phase 1/2 clinical proof-of-concept data for RLYB211 was presented at the International Society on Thrombosis and Haemostasis (ISTH) 2021 Virtual Congress. RLYB211 is a polyclonal anti-HPA-1a antibody in development for the prevention of fetal and neonatal alloimmune thrombocytopenia (FNAIT). The data presented at ISTH demonstrated the ability of an anti-HPA-1a antibody to rapidly and completely clear HPA-1a positive platelets from the circulation of HPA-1a negative participants. Based on these results, Rallybio believes that administration of an anti-HPA-1a antibody could be a viable approach for the prevention of FNAIT. In addition, treatment with RLYB211 was safe and well tolerated, and no serious adverse events were observed. The poster presentation can be accessed on Rallybio’s website here.
- In August 2021, Rallybio closed its initial public offering (IPO) of 7,130,000 shares of common stock at a public offering price of $13.00 per share. The aggregate gross proceeds to Rallybio from the offering were approximately $92.7 million, before deducting underwriting discounts, commissions and other offering expenses.

Upcoming Milestones:

- Rallybio is on-track to initiate a natural history study of FNAIT in the third quarter of 2021.
- Rallybio plans to announce additional clinical data from the ongoing Phase 1/2 clinical trial of RLYB211 in the fourth quarter of 2021.
- Rallybio remains on-track to initiate a Phase 1 study of RLYB212 in the first quarter of 2022. RLYB212 is a monoclonal anti-HPA-1a antibody in development for the prevention of FNAIT.

- Rallybio remains on-track to initiate a Phase 1 study of RLYB116 in the first quarter of 2022. RLYB116 is a novel, potentially long-acting, subcutaneously administered inhibitor of complement factor 5, or C5, in development for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) and generalized Myasthenia Gravis (gMG).

Second Quarter and First Half 2021 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $6.8 million for the second quarter of 2021, compared to $3.1 million for the same period in 2020. For the six months ending June 30, 2021, R&D expenses were $15.9 million, compared to $5.0 million for the same period in 2020. This increase in R&D expenses for both the three and six months ended June 30, 2021 as compared to the same periods ended June 30, 2020 was primarily due to an increase in development costs associated with RLYB212 and RLYB116. In addition, for both the three and six months ended June 30, 2021 as compared to the same periods ended June 30, 2020, there was an increase in personnel-related costs, including equity-based compensation.
- **General & Administrative (G&A) Expenses:** G&A expenses were $3.7 million for the second quarter of 2021, compared to $1.6 million for the same period in 2020. For the six months ending June 30, 2021, G&A expenses were $7.5 million, compared to $3.5 million for the same period in 2020. The increase in G&A expenses for both the three and six months ended June 30, 2021 as compared to the same periods ended June 30, 2020 was primarily due to an increase in payroll and personnel-related costs, including equity-based compensation, primarily due to an increase in G&A related headcount and other professional fees associated with operating activities and preparations for becoming a public company.
- **Net Loss Attributable to Common Units:** Net loss was $11.1 million for the second quarter of 2021, or a net loss per common unit of $2.80, as compared to a net loss of $4.9 million for the second quarter of 2020, or a net loss per common unit of $1.85. Net loss was $24.4 million for six months ended June 30 2021, or a net loss per common unit of $6.77, as compared to a net loss of $8.8 million for the six months ended June 30 2020, or a net loss per common unit of $3.81. The net loss per common unit for all periods disclosed does not give effect to the completion of the Reorganization or the Company's IPO that was closed in August 2021. See Financial tables for additional information on the Reorganization.
- **Cash Position:** As of June 30, 2021, cash, cash equivalents and short-term investments were $112.7 million. This amount does not include total net proceeds from the IPO of approximately $83.2 million, after deducting underwriting discounts, commissions and other offering expenses, which closed in August 2021.

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, the initiation and timing of our planned clinical trials, including our clinical trials for RLYB212, and RLYB116, and the natural history study for our FNAIT

prevention program, and the period during which the results of the trials will become available or announced. 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 clinical trials for RLYB212 and 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 final prospectus for its initial public offering dated July 28, 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 HOLDINGS, LLC AND SUBSIDIARIES[1]

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(in thousands, except units and per unit amounts)	THREE MONTHS ENDED JUNE 30, 2021	THREE MONTHS ENDED JUNE 30, 2020	SIX MONTHS ENDED JUNE 30, 2021	SIX MONTHS ENDED JUNE 30, 2020
Operating Expenses:				
Research and development	$ 6,818	$ 3,092	$ 15,855	$ 5,005
General and administrative	3,712	1,570	7,499	3,501
Total operating expenses	10,530	4,662	23,354	8,506
Loss from operations	(10,530)	(4,662)	(23,354)	(8,506)
Other income (expenses):				
Interest income	13	47	30	102
Interest expense	—	(12)	(10)	(24)
Other (expense) income	(142)	69	(118)	121
Total other (expense) income, net	(129)	104	(98)	199
Loss before income taxes	(10,659)	(4,558)	(23,452)	(8,307)
Income tax benefit	—	—	—	(16)
Loss on investment in joint venture	468	335	950	483
Net loss and comprehensive loss	$ (11,127)	$ (4,893)	$ (24,402)	$ (8,774)
Net loss attributable to common units	$ (11,127)	$ (4,893)	$ (24,402)	$ (8,774)
Net loss per common unit, basic and diluted [2]	$ (2.80)	$ (1.85)	$ (6.77)	$ (3.81)
Weighted average common units outstanding, basic and diluted [2]	3,978,054	2,643,750	3,603,193	2,304,385

RALLYBIO HOLDINGS, LLC AND SUBSIDIARIES[(1)]

Condensed Consolidated Balance Sheets

(Unaudited)

(in thousands)	JUNE 30, 2021	DECEMBER 31, 2020
Cash and cash equivalents	$ 112,729	$ 140,233
Total assets	$ 120,097	$ 141,858
Total liabilities	$ 7,435	$ 5,855
Total members' deficit	$ (69,365)	$ (46,024)
Total liabilities, redeemable convertible preferred units, and members' deficit	$ 120,097	$ 141,858

(1) Prior to our IPO, we operated as Rallybio Holdings, LLC, a Delaware limited liability company (Rallybio Holdings). On June 30, 2021, we completed a series of transactions pursuant to which (i) Rallybio IPD, LLC, a direct subsidiary of Rallybio Holdings, was converted from a Delaware limited liability company to a Delaware corporation and changed its name to Rallybio Corporation (the Corporation) and (ii) four direct subsidiaries of the 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 the Corporation in exchange for its interest in each Asset Subsidiary, which resulted in the Asset Subsidiaries becoming subsidiaries of the Corporation and the 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 the Corporation, consisting solely of common stock, to the unitholders of Rallybio Holdings. The liquidation of Rallybio Holdings and distribution of the capital stock of the Corporation to the unitholders of Rallybio Holdings is referred to as the "Liquidation" and the Liquidation and these other transactions are collectively referred to as the "Reorganization." As a result of the Reorganization, the unitholders of Rallybio Holdings became the holders of common stock of the Corporation, and our consolidated financial statements are subsequently reported from the Corporation. The unaudited condensed consolidated financial statements for the three and six months ended June 30, 2021 and 2020 are those of the Rallybio Holdings and do not give effect to the Reorganization.

(2) The net loss per common unit for all periods disclosed does not give effect to the completion of the Reorganization or the company's IPO that was closed in August 2021.

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