# 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): November 10, 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 November 10, 2021, Rallybio Corporation issued a press release announcing its financial results for the quarter ended September 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 November 10, 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: November 10, 2021

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

**Exhibit 99.1**

**Rallybio Corporation Reports Third Quarter 2021 Financial Results and Recent Business Highlights**

*-- Initiated FNAIT natural history study to inform frequency of FNAIT risk in broad population and support future potential registration trial --*
*-- On-track to announce in 4Q 2021 additional clinical data from ongoing Phase 1/2 study of RLYB211 for prevention of FNAIT --*
*-- Executing across preclinical portfolio, with Phase 1 studies for RLYB212 and RLYB116 expected to initiate in 1Q 2022 --*

New Haven, Conn. – November 10, 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 financial results for the third quarter ended September 30, 2021 and provided an update on recent corporate developments.

“We continue to work with unwavering commitment to deliver transformative impact to people living with severe and rare disorders,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. “In the third quarter, our team focused on execution across our FNAIT franchise and advanced our efforts to better define the patient populations most at risk for disease through the initiation of our natural history study, while continuing to progress RLYB212 toward the clinic for the first quarter of 2022. We plan to report data from our ongoing Phase 1/2 trial of RLYB211 in the fourth quarter, which will provide further insight into the relationship between treatment duration and platelet clearance as well as inform our clinical development strategy for RLYB212. In parallel, we continue to advance efforts across our broader portfolio. We expect to initiate a Phase 1 study of RLYB116, our lead C5 inhibitor, in the first quarter of 2022, and we continue to pursue the best science around the globe to expand our pipeline with new assets and partners.”

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 September 2021, Rallybio initiated a fetal and neonatal alloimmune thrombocytopenia (FNAIT) natural history alloimmunization study. The prospective, non-interventional, multinational study is designed to determine the frequency of women at higher FNAIT risk among expectant mothers of different racial and ethnic characteristics, as well as the frequency of HPA-1a alloimmunization and pregnancy outcomes among women identified to be at higher FNAIT risk. Data from this study will be used to support a future registration trial for RLYB212, by providing historical controlled data to support a single-arm Phase 2/3 registration trial design, operationalizing *de novo* the laboratory test paradigm for FNAIT risk, and generating FNAIT laboratory test performance data for future regulatory discussions.

**Upcoming Milestones:**

- 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 expects 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).

**Third Quarter 2021 Financial Results:**

- **Research & Development (R&D) Expenses:** R&D expenses were $5.0 million for the third quarter of 2021, compared to $5.1 million for the same period in 2020. Consistent research and development expense for the three months ended September 30, 2021 as compared to September 30, 2020 was primarily driven by decreases in development costs of RLYB116 and RLYB211 offset by increases in preclinical development costs of RLYB114.
- **General & Administrative (G&A) Expenses:** G&A expenses were $5.0 million for the third quarter of 2021, compared to $1.6 million for the same period in 2020. The increase in general and administrative expenses for three months ended September 30, 2021 as compared to September 30, 2020 was primarily due to additional G&A related headcount, increased non-cash share-based compensation expense, and an increase of other professional fees associated with operating activities and becoming a public company.
- **Net Loss and Net Loss Per Common Share:** Net loss was $10.2 million for the third quarter of 2021, or a net loss per common share of $0.37, as compared to a net loss of $7.2 million for the third quarter of 2020, or a net loss per common share of $0.32.
- **Cash Position:** As of September 30, 2021, cash and cash equivalents were $187.0 million. This amount includes total net proceeds from the Company's August 2021 initial public offering, which raised approximately $83.0 million, after deducting underwriting discounts, commissions and other offering costs.

**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, 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 Quarterly Report on Form 10-Q for the period ended June 30, 2021 filed on September 9, 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**

**Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited) [1]**

| (in thousands, except share and per share amounts) | THREE MONTHS ENDED SEPTEMBER 30, 2021 | THREE MONTHS ENDED SEPTEMBER 30, 2020 | NINE MONTHS ENDED SEPTEMBER 30, 2021 | NINE MONTHS ENDED SEPTEMBER 30, 2020 |
|---|---|---|---|---|
| Operating expenses: | | | | |
| Research and development | $ 4,960 | $ 5,130 | $ 20,815 | $ 10,135 |
| General and administrative | 5,021 | 1,580 | 12,520 | 5,081 |
| Total operating expenses | 9,981 | 6,710 | 33,335 | 15,216 |
| Loss from operations | (9,981) | (6,710) | (33,335) | (15,216) |
| Other income (expenses): | | | | |
| Interest income | 12 | 42 | 42 | 144 |
| Interest expense | — | (13) | (10) | (37) |
| Other income (expense) | 105 | 52 | (13) | 173 |
| Total other income, net | 117 | 81 | 19 | 280 |
| Loss before income taxes | (9,864) | (6,629) | (33,316) | (14,936) |
| Income tax benefit | — | — | — | (16) |
| Loss on investment in joint venture | 332 | 526 | 1,282 | 1,009 |
| Net loss and comprehensive loss | $ (10,196) | $ (7,155) | $ (34,598) | $ (15,929) |
| Net loss per common share, basic and diluted | $ (0.37) | $ (0.32) | $ (1.44) | $ (1.01) |
| Weighted average common shares outstanding, basic and diluted | 27,527,770 | 22,142,148 | 24,011,862 | 15,772,918 |

**RALLYBIO CORPORATION**

**Condensed Consolidated Balance Sheets (Unaudited) [1]**

| (in thousands) | SEPTEMBER 30, 2021 | DECEMBER 31, 2020 |
|---|---|---|
| Cash and cash equivalents | $ 186,978 | $ 140,233 |
| Total assets | 193,865 | 141,858 |
| Total liabilities | 7,379 | 5,855 |
| Total stockholders' equity | 186,486 | 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.