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): April 9, 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 1.01 Entry into a Material Definitive Agreement.

Collaboration Agreement

On April 9, 2024, Rallybio Corporation (the "Company"), through its subsidiary Rallybio IPA, LLC, entered into a collaboration agreement (the "Collaboration Agreement") with Johnson & Johnson, through its wholly-owned subsidiary, Momenta Pharmaceuticals, Inc. ("J&J"), pursuant to which the Company and J&J will advance therapeutic solutions for pregnant individuals at risk of fetal and neonatal alloimmune thrombocytopenia ("FNAIT"). Under the Collaboration Agreement, the Company will share certain aggregated, anonymized data with J&J, collected from the Company's FNAIT natural history study and the Company's planned Phase 2 FNAIT clinical trial that will be restricted to collection of certain natural history data in support of the FNAIT natural history study. The Company also agreed to disseminate information to its FNAIT study sites related to J&J's and its affiliates' research and development of complementary therapeutic approaches aimed at reducing the risk of FNAIT.

Under the terms of the Collaboration Agreement, J&J will provide an upfront payment to the Company of $0.5 million. The Company is also eligible to receive additional payments of up to an aggregate of $3.7 million, based upon certain triggers relating to the FNAIT studies and the Company's activities under the Collaboration Agreement.

The Collaboration Agreement expires on April 9, 2026. The Company may terminate the Collaboration Agreement upon J&J's material breach, the Company's decision to discontinue an FNAIT study, or during a certain part of the term if the Company determines for any reason that termination of the Collaboration Agreement is in the best interests of the Company. J&J may terminate the Collaboration Agreement upon the Company's material, uncured breach, upon the Company's decision to discontinue an FNAIT study, documented failure of the Company to conduct its FNAIT studies in accordance with applicable law and J&J's decision to discontinue its FNAIT studies.

Private Placement

On April 10, 2024, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with Johnson & Johnson Innovation – JJDC, Inc., a Delaware corporation (the "Purchaser"), pursuant to which the Company sold to the Purchaser, in an unregistered offering (the "Offering"), shares of common stock, par value $0.0001 per share (the "Common Stock"). The closing of the Offering (the "Closing") occurred on April 10, 2024.

Pursuant to the Purchase Agreement, the Company agreed to sell 3,636,363 shares of Common Stock (the "Shares") to the Purchaser for aggregate gross proceeds to the Company of approximately $6.6 million, before deducting estimated offering expenses payable by the Company.

In connection with the Offering, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchaser pursuant to which the Company agreed, among other things, to file with the Securities and Exchange Commission a registration statement covering the resale of the Shares within 120 days following the Closing, and to use commercially reasonable efforts to cause such registration statement to become effective on or prior to 30 calendar days after the filing of the registration statement.

Further, the Company and the Purchaser entered into a lock-up agreement, pursuant to which the Purchaser agreed not to effect any sale or other transfer of the Company's Common Stock for 180 days following the Closing, subject to certain customary exceptions.

The foregoing summaries of the Collaboration Agreement, the Offering, the securities to be issued in connection with the Offering and the Purchase Agreement do not purport to be complete and are qualified in their entirety by reference to the definitive transaction documents, copies of which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024.

Item 3.02 Unregistered Sales of Equity Securities.

To the extent required by Item 3.02 of Form 8-K, the information regarding the Shares set forth under Item 1.01 of this Form 8-K is incorporated by reference in this Item 3.02. The Company issued the Shares in reliance on the exemption from registration provided for under Rule 506(c) of Regulation D promulgated under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). The Company relied on this exemption from registration for private placements based in part on the representations made by the Purchaser, including the representations with respect to the Purchaser's status as an accredited investor, as such term is defined in Rule 501(a) of the Securities Act, and the Purchaser's investment intent. The offer and sale of the Shares have not been registered under the Securities Act.

Item 7.01 Regulation FD Disclosure.

On April 10, 2024, the Company issued a press release announcing the Collaboration Agreement and the Offering. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information contained in this Item 7.01, including Exhibit 99.1, is deemed to have been furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and is not incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on April 10, 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: April 10, 2024

By: /s/ Jonathan I. Lieber

Jonathan I. Lieber
Chief Financial Officer and Treasurer

Exhibit 99.1

Rallybio Announces Collaboration to Advance Therapeutic Solutions for Pregnant Individuals at Risk of Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT)

— Rallybio to Receive Funding for FNAIT Awareness Initiative and Equity Investment from Johnson & Johnson —

NEW HAVEN, Conn., April 10, 2024 – 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 announced a collaboration with Johnson & Johnson[1] to support the development of complementary therapeutic approaches aimed at reducing the risk of fetal and neonatal alloimmune thrombocytopenia (FNAIT). In addition, Rallybio received an equity investment of $6.6 million from Johnson & Johnson Innovation – JJDC, Inc.

Rallybio is developing RLYB212, a novel human monoclonal anti-HPA-1a antibody designed to prevent pregnant individuals from alloimmunizing[2], thereby eliminating the risk of FNAIT and its potentially devastating consequences in their fetuses and newborns. Rallybio is on track to initiate a Phase 2 dose confirmation study for RLYB212 in pregnant individuals at higher risk of alloimmunization and FNAIT in the second half of 2024.

Under this collaboration, Johnson & Johnson will provide funding for Rallybio to raise awareness of Johnson & Johnson's FNAIT clinical program in connection with Rallybio's ongoing FNAIT natural history study. Rallybio is also eligible to receive additional payments under the collaboration.

RLYB212 is the only investigational therapy currently reported to be in clinical development to address the needs of pregnant individuals at risk of FNAIT who have not alloimmunized[2]. Johnson & Johnson is conducting a Phase 3 study of nipocalimab, an investigational monoclonal antibody targeting FcRn, in pregnant individuals who are already alloimmunized. As these individuals have the alloantibodies that can cause FNAIT, preventative treatment with RLYB212 would not be appropriate.

"We are thrilled to be working with Johnson & Johnson on our mission to eliminate FNAIT," said Stephen Uden, M.D., Chief Executive Officer of Rallybio. "Our complementary approaches, if successful, would ensure that pregnant individuals at risk of developing FNAIT have a potential treatment option – regardless of their alloimmunization status. Together, we can more effectively and expeditiously drive awareness of FNAIT, emphasize the importance of screening pregnant individuals for their risk of developing FNAIT, and advance our complementary therapeutic approaches."

Rallybio is currently conducting a natural history study designed to provide a contemporary dataset for HPA-1a alloimmunization frequency in a racially and ethnically diverse population

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[1] FNAIT Collaboration Agreement between Momenta Pharmaceuticals, Inc., a Johnson & Johnson Company, and Rallybio IPA, LLC.

[2] Alloimmunizing: an immune response to foreign antigens upon exposure to genetically different cells or tissues

that is intended to support a future RLYB212 registration study. Pregnant individuals who are already alloimmunized are not eligible for inclusion in Rallybio's natural history study, nor for potential preventative treatment with Rallybio's investigational therapeutic, RLYB212.

About FNAIT
Fetal and Neonatal Alloimmune Thrombocytopenia (FNAIT) is a potentially life-threatening rare disease that can cause uncontrolled bleeding in fetuses and newborns. FNAIT can arise during pregnancy due to an immune incompatibility between an expectant mother and her fetus in a platelet antigen. When alloimmunization occurs in an expectant mother, the antibodies that develop in the mother can cross the placenta and destroy platelets in the fetus. The destruction of platelets in the fetus can result in severely low platelet counts, or thrombocytopenia, and potentially lead to devastating consequences including miscarriage, stillbirth, death of the newborn, or severe lifelong neurological disability in those babies who survive. There is currently no approved therapy for the prevention or prenatal treatment of FNAIT.

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 study for RLYB212, the release of screening numbers of women in the natural history study, and whether the results of the natural history study and the planned Phase 2 dose confirmation study will be sufficient to support design and implementation of a Phase 3 registrational study for RLYB212 . 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 studies, and complete such clinical studies 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 Annual Report on Form 10-K for the period ended December 31, 2023, 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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