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): May 5, 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 1.01. Entry Into a Material Definitive Agreement.

On May 5, 2022, Rallybio Corporation's subsidiary, Rallybio IPE, LLC (Rallybio), entered into a License Agreement (License Agreement) with Kymab Limited (Sanofi). Under the License Agreement, Sanofi provides Rallybio with worldwide exclusive rights to Sanofi's KY1066, which will be referred to as RLYB331. Under the terms of the License Agreement, Rallybio has an exclusive license to certain Sanofi patents to develop, manufacture and commercialize RLYB331 and Rallybio agrees to use commercially reasonable efforts to develop and commercialize a licensed product in at least one indication in the field in each of several major markets, as described in the License Agreement.

The License Agreement provides that Rallybio will make an upfront cash payment to Sanofi of $3 million. In addition, Rallybio has agreed to pay Sanofi up to an aggregate of $43 million in development and regulatory milestones and up to an aggregate of $150 million in commercial milestones for a product in its first indication, plus tiered low-to-mid double digit percentages of such milestone amounts for up to three additional indications, and mid to high single digit royalties on net sales.

The License Agreement contains other customary license terms including related to sublicensing, development, regulatory, manufacturing, commercialization, milestones, royalties, intellectual property, and termination. The License Agreement will expire on a product-by-product and country-by-country basis at the end of the applicable royalty term. Either party may terminate the License Agreement upon material breach of the License Agreement by the other, subject to a cure period. Rallybio may terminate the License Agreement for convenience upon 90 days prior written notice to Sanofi. Sanofi may terminate the License Agreement immediately in the case of Rallybio's insolvency, bankruptcy or a similar event, or if Rallybio or its affiliates participates in any proceeding challenging the validity of the licensed patents.

If the License Agreement is terminated in its entirety, among other things (a) all rights and licenses granted by Sanofi under the License Agreement (including any sublicenses) will terminate and (b) if Sanofi has an interest in developing, manufacturing and commercializing the licensed compounds or products, the parties to the License Agreement shall negotiate an arrangement to provide Sanofi rights to the patents, know-how, materials and other properties controlled by Rallybio applicable to any of the licensed product. The foregoing is a summary of the terms of the License Agreement and is qualified in its entirety by reference to the License Agreement, a copy of which will be filed as an exhibit to Rallybio Corporation's Quarterly Report on Form 10-Q for the period ended June 30, 2022.

Item 2.02 Results of Operations and Financial Condition.

On May 10, 2022, Rallybio Corporation issued a press release announcing its financial results for the quarter ended March 31, 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 8.01. Other Events.

On May 10, 2022, Rallybio Corporation issued a press release announcing the License Agreement with Sanofi. A copy of the press release is attached hereto as exhibit 99.2.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on May 10, 2022 regarding financial results for the quarter ended March 31, 2022
99.2	Press release issued by the Company on May 10, 2022 regarding the Sanofi License Agreement
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: May 10, 2022

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

Exhibit 99.1

Rallybio Reports First Quarter 2022 Financial Results

-- Initiated Phase 1b proof-of-concept study for RLYB212 for the prevention of FNAIT; initial data expected in 3Q 2022 --

-- Phase 1 study of RLYB116 ongoing; initial single dose safety, PK, and PD data expected in 2H 2022 --

-- Acquired RLYB331 from Sanofi, a potentially first-in-class antibody for the treatment of multiple severe anemias with ineffective erythropoiesis and iron overload--

NEW HAVEN, Conn. May 10, 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 first quarter ended March 31, 2022 and provided an update on recent program and corporate developments.

“We continue to move forward with our mission of discovering, developing, manufacturing and delivering therapies that meaningfully improve the lives of people with devastating rare diseases,” said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. “We announced this morning that we completed our first acquisition as a public company, in-licensing RLYB331, a highly differentiated product candidate that could transform the treatment of severe, non-malignant hematological disorders. This transaction is an excellent example of our strategy of expanding our pipeline by investing in assets that have a clear mechanism of action, address a significant unmet patient need, and are complementary to our existing portfolio.”

Dr. Mackay continued, “In parallel, we advanced our two clinical-stage programs, RLYB212 and RLYB116. We are pleased to announce today the initiation of the Phase 1b proof-of-concept study of RLYB212, which is designed to establish the ability of RLYB212 to rapidly eliminate transfused HPA-1a positive platelets from HPA-1a negative healthy subjects. We look forward to reporting data from this study, as well as our ongoing Phase 1 study of RLYB116, later this year.”

Recent Business Highlights and Upcoming Milestones:

Maternal Fetal Blood Disorders

In January 2022, Rallybio announced that the first subjects were dosed in the 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). This single-blind, placebo-controlled Phase 1 study is designed to evaluate the safety and pharmacokinetics (PK) of single and repeat subcutaneous doses of RLYB212 in HPA-1a negative healthy subjects.

The Company announced today that it has now 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. Rallybio expects initial data from this proof-of-concept study in the third quarter of 2022.

In parallel, Rallybio continues to advance the FNAIT natural history alloimmunization study, with the first patient screened in March 2022. 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 also plans that the data from this study contribute to a control dataset for a future single armed registration trial for RLYB212.

Complement Dysregulation

In the first quarter of 2022, 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. The single-blind, placebo-controlled dose escalation study is designed to evaluate the safety, PK, and pharmacodynamics of single dose RLYB116 in healthy volunteers and remains on track, with initial data expected in the second half 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 announced today that it has obtained worldwide exclusive rights to Sanofi's KY1066, now referred to as RLYB331, a preclinical potentially first-in-class antibody. RLYB331 has the potential to address a significant unmet need for patients with severe anemias with ineffective erythropoiesis and iron overload including beta thalassemia and a subset of myelodysplastic syndromes. Currently these patients are underserved by the existing standard of care.

RLYB331 is a monoclonal antibody that inhibits Matriptase-2 (MTP-2). The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis.

Rallybio plans to initiate IND-enabling activities for RLYB331 to support transition of the asset into clinical development.

Corporate

In April 2022, Rallybio announced the appointments of Christine Nash, MBA and Hui Liu, Ph.D., to its Board of Directors. Ms. Nash currently serves as Board Chair and senior advisor to the President and CEO at The CM Group and brings nearly 20 years of commercial and product launch experience in rare diseases. Dr. Liu is the Executive Vice President, Chief Business Officer and Head of U.S. at Merus N.V., with 25 years of experience in business development, finance, and strategy. In conjunction with these appointments, Rallybio also announced that Tim Shannon, M.D., will resign from Rallybio's Board of Directors, effective May 24, 2022.

First Quarter 2022 Financial Results:

- **Research & Development (R&D) Expenses:** R&D expenses were $7.6 million for the first quarter of 2022, compared to $9.0 million for the same period in 2021. The decrease in R&D expense for the three months ended 2022 as compared to 2021 were a result of a decrease in clinical manufacturing expenses of RLYB212 and RLYB116 partially offset by increases in preclinical research development costs of RLYB114 and increases in R&D payroll and personnel-related expenses.
- **General & Administrative (G&A) Expenses:** G&A expenses were $6.7 million for the first quarter of 2022, compared to $3.8 million for the same period in 2021. The increase is primarily related to an increase in payroll and personnel-related costs due to an increase in general and administrative related headcount, including an increase of $1.0 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 $14.5 million for the first quarter of 2022, or net loss per common share of $0.48 compared to a net loss of $13.3 million, or net loss per common share of $0.60 for the first quarter of 2021.
- **Cash Position:** As of March 31, 2022, cash, cash equivalents, and marketable securities were $161.4 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.

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 MARCH 31, 2022	2021
Operating expenses:		
Research and development	$ 7,648	$ 9,037
General and administrative	6,670	3,787
Total operating expenses	14,318	12,824
Loss from operations	(14,318)	(12,824)
Other income (expenses):		
Interest income	97	17
Interest expense	—	(10)
Other income	113	24
Total other income, net	210	31
Loss from continuing operations	(14,108)	(12,793)
Loss on investment in joint venture	390	482
Net loss	$ (14,498)	$ (13,275)
Net loss per common share, basic and diluted	$ (0.48)	$ (0.60)
Weighted average common shares outstanding, basic and diluted	30,318,405	22,244,883
Other comprehensive loss:		
Net unrealized loss on marketable securities	122	—
Other comprehensive loss	(122)	—
Comprehensive loss	$ (14,620)	$ (13,275)

Condensed Consolidated Balance Sheets (Unaudited)

(in thousands)	MARCH 31, 2022	DECEMBER 31, 2021
Cash, cash equivalents, and marketable securities	$ 161,409	$ 175,334
Total assets	169,353	182,185
Total liabilities	6,317	6,583
Total stockholders' equity	163,036	175,602

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Exhibit 99.2

Rallybio Announces In-Licensing of Potential First-In-Class Preclinical Antibody Candidate from Sanofi

--Expands pipeline focus on rare benign hematological disorders--

--Licensing agreement marks first business development transaction since IPO—

NEW HAVEN, Conn. May 10, 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 announced that it has obtained worldwide exclusive rights to Sanofi's KY1066, which will be referred to as RLYB331 going forward, a preclinical potentially first-in-class antibody. RLYB331 has the potential to address a significant unmet need for patients with severe anemia with ineffective erythropoiesis and iron overload, such as beta thalassemia (BT) and a subset of myelodysplastic syndromes (MDS), amongst others. The transaction expands Rallybio's pipeline, is strategically consistent with Rallybio's existing focus on hematology, and aligns with its mission to accelerate the development of life-transforming therapies for patients with severe and rare disorders.

"With our strong focus on portfolio expansion, the in-licensing of RLYB331, our first as a public company, marks a pivotal moment for Rallybio. We believe RLYB331 is differentiated from all programs in clinical development based on its mechanism of action, with the potential to be first-in-class. We expect that RLYB331 may address a significant unmet need by correcting ineffective erythropoiesis, improving hemoglobin, reducing red blood cell transfusions and reducing iron overload in multiple hematological disorders such as beta thalassemia and myelodysplastic syndromes," said Martin Mackay, Ph.D., Chief Executive Officer of Rallybio. "This product candidate is a natural fit with our R&D expertise and our focus on hematological disorders. Along with our existing pipeline it provides an additional opportunity to leverage our deep expertise in rare diseases and to identify and accelerate the development of transformative therapies for patients with severe and rare diseases. We look forward to integrating RLYB331 into our portfolio and ultimately deliver this therapy to transform the treatment of patients with severe benign hematological disorders."

RLYB331 is a monoclonal antibody that inhibits Matriptase-2 (MTP-2). The inhibition of MTP-2 significantly increases levels of hepcidin, decreases iron load and treats ineffective erythropoiesis. The standard of care for many such hematological disorders leaves a significant unmet need in iron overload associated anemias with patients experiencing significant morbidity and consequent mortality.

Rallybio plans to prosecute preclinical activities for RLYB331 including CMC, and dose-range finding and toxicity studies, which will then support transition of the asset into clinical development.

Under the terms of the license agreement, Rallybio will make an upfront cash payment of $3 million to Sanofi, in addition to development and commercial milestones, and mid to high single digit royalties on net sales.

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