UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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 9, 2024

REZOLUTE, INC.
(Exact Name of Registrant as Specified in Charter)

Nevada	001-39683	27-3440894
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

275 Shoreline Drive, Suite 500, Redwood City, CA 94065
(Address of Principal Executive Offices, and Zip Code)

650-206-4507
Registrant's Telephone Number, Including Area Code

Not Applicable
(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 (*see* General Instruction A.2. below):

☐ Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communication 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 $0.001 per share	**RZLT**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 7.01 Regulation FD Disclosure.

On September 9, 2024, Rezolute, Inc. issued a press release to announce that the U.S. Food and Drug Administration has completely removed the partial clinical holds on RZ358 (ersodetug) for the treatment of hypoglycemia as a result of congenital hyperinsulinism.

The information 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 liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 9, 2024

104	Cover Page Interactive Data File (formatted as inline XBRL)

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 hereunto duly authorized.

REZOLUTE, INC.

DATE: September 9, 2024

By: */s/Nevan Charles Elam*
Nevan Charles Elam
Chief Executive Officer

Exhibit 99.1

FDA Lifts Partial Clinical Holds on RZ358 for the Treatment of Congenital Hyperinsulinism and Authorizes U.S. Inclusion in Ongoing Phase 3 Study

Commencing study startup activities in the U.S.; participant enrollment anticipated in early 2025

REDWOOD CITY, Calif., September 9, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage rare disease company developing a novel therapy to treat hyperinsulinism (HI), today announced that the U.S. Food and Drug Administration (FDA) has removed the partial clinical holds on RZ358 (ersodetug), a potential treatment for hypoglycemia caused by congenital HI.

Ersodetug is currently being studied in sunRIZE, a Phase 3, multi-center, double-blind, randomized, placebo-controlled, safety and efficacy registrational study in participants with congenital HI. The Company will now commence study start-up activities in the U.S. with the goal of including U.S. participants in the global sunRIZE study. The Company anticipates potential U.S. enrollment to begin in early 2025, which will enable announcement of topline data from the study in the second half of 2025.

"We are delighted that FDA has completely removed the partial clinical holds and are allowing us to proceed in the U.S. at all doses and in participants as young as three months of age as part of our ongoing global study. Of note, FDA specifically concluded that the liver toxicity observed in Sprague Dawley rats is likely strain-specific and not otherwise relevant to humans," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "Coming on the heels of our recent announcement of FDA clearance of a separate Phase 3 study in tumor-associated HI, we are in the unique and fortunate position to be advancing ersodetug in two Phase 3 rare disease programs in the U.S. and globally."

For more information on ersodetug and our programs in congenital HI and tumor HI, please visithttps://www.rezolutebio.com/pipeline/.

About Ersodetug

Ersodetug is a fully human monoclonal antibody that binds to a unique allosteric site on insulin receptors to counteract the effects of insulin receptor over-activation by insulin and related substances (such as IGF-2), thereby improving hypoglycemia in the setting of hyperinsulinism. Because ersodetug acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to any form of HI.

About sunRIZE

The Phase 3 sunRIZE study is a multi-center, randomized, double-blind, placebo-controlled, parallel arm study designed to evaluate the efficacy and safety of ersodetug in patients with congenital HI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study is enrolling up to 56 participants in more than a dozen countries around the world.

Forward-Looking Statements

Any statements in this press release about the Company's future expectations, plans and prospects, including statements regarding the public offering, constitute forward-looking statements for purposes of the safe harbor provisions under the Private Securities Litigation Reform Act of 1995. Forward-looking statements include any statements about the Company's strategy, future operations and future expectations and plans and prospects for the Company, and any other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. These forward-looking statements include statements about RZ358 as a sunRIZE Phase 3 study, the Phase 2 RIZE study, the complete removal of the partial clinical holds on RZ358 (ersodetug) for the treatment of hypoglycemia, the ability of RZ358 to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of the RZ358 to become an effective treatment for congenital hyperinsulinism, and statements regarding the timeliness of the ongoing global Phase 3 sunRIZE study. These forward-looking statements are based on information currently available to the Company and its current plans or expectations, and are subject to a number of uncertainties and risks that could significantly affect current plans. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, those related to market and other financial conditions, and other factors discussed in the "Risk Factors" section contained in the reports that the Company files with the SEC. Any forward-looking statements represent the Company's views only as of the date of this press release. The Company anticipates that subsequent events and developments will cause its views to change. While the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so except as required by law.

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