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): December 13, 2023

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 December 13, 2023, Rezolute, Inc. issued a press release announcing completion of enrollment in its Phase 2 clinical study of RZ402 in diabetic macular edema. Additionally on December 14, 2023, Rezolute, Inc. issued a press release announcing the first clinical site activations of a pivotal Phase 3 clinical study of RZ358 in patients with congenital hyperinsulinism A copy of these press releases are attached hereto as Exhibit 99.1 and Exhibit 99.2.

The information in this Current Report on Form 8-K, including Exhibit 99.1 and Exhibit 99.2, 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 December 13, 2023

99.2	Press Release, dated December 14, 2023
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: December 14, 2023

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

Exhibit 99.1

Rezolute Completes Enrollment of its Phase 2 Study in Diabetic Macular Edema ("DME")

Plans to report topline data mid-second quarter 2024

Redwood City, Calif., December 13, 2023 -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced the completion of enrollment in its RZ402 Phase 2 study in diabetic macular edema ("DME"). RZ402 is a selective and potent plasma kallikrein inhibitor ("PKI") being developed as a potential oral therapy for the chronic treatment of DME.

The study is a multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a once daily oral monotherapy over a 12-week treatment period and four-week follow-up in participants with DME who are naïve to, or have received limited anti-VEGF injections. Eligible participants were randomized equally to either a placebo control arm or one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg.

This proof-of-concept study was designed to enroll up to 100 participants to evaluate activity and safety by individual dose level and in pooled fashion. In the fourth quarter 2023, based on considerable momentum, the Company elected to keep enrollment open into December to include as many eligible patients as possible. Screening is now complete, and final study enrollment is expected to be approximately 95 participants. Additionally, although each participant has an assigned study eye, it is expected that a meaningful number of non-study eyes will be eligible for evaluation. Since DME results from a systemic vascular complication associated with diabetes, it commonly affects both eyes. RZ402, as an orally available systemic therapy, has the potential to treat both eyes simultaneously. As a result of the extension of the enrollment period, the Company now plans to report topline results in the middle of the second quarter 2024, rather than the end of the first quarter 2024.

"The strong commitment from our participating clinical trial sites and equally strong conclusion of study enrollment are indicative of the high demand and unmet medical need for an oral therapy and new mechanistic target for the chronic treatment of DME," remarked Dr. Brian Roberts, Chief Medical Officer of Rezolute. "We are incredibly excited and thankful for the level of the engagement that we have received from the retina community and wish to thank the study investigators, their study staff, and the patient participants who trailblaze new therapies. We very much look forward to reporting the results from this study in the coming months."

The principal endpoints of the trial include (i) the change in central subfield thickness of the macula, as measured by Spectral Domain Ocular Coherence Tomography, (ii) the change in best-corrected visual acuity as measured by the early treatment diabetic retinopathy scale, (iii) the repeat dose pharmacokinetics of RZ402 in patients with DME, and (iv) the safety and tolerability of RZ402.

DME is a result of a systemic microvascular complication of diabetes, manifesting in the retinal blood vessels behind the eyes, and therefore commonly affects both eyes. With currently available intravitreal anti-VEGF therapies, two separate eye injections are required, or treatment of one eye or both eyes may be deferred, when both eyes are affected. Although a single study eye was identified for primary evaluation, Rezolute plans to take advantage of the binocular exposure that is achieved with its oral therapy and will also evaluate key endpoints in the non-study eye.

About RZ402

RZ402 is a selective and potent PKI being developed as a potential once-daily oral therapy for the chronic treatment of DME. By inhibiting the activation of kallikrein, RZ402 is designed to block bradykinin production and its resulting effects on vascular leakage and inflammation.

RZ402 has been shown to reduce and prevent retinal vascular leakage in animal models by up to 90%. Results from a Phase 1b multiple ascending dose (MAD) study showed that RZ402 was readily bioavailable with dose-dependent increases in systemic exposures. RZ402 concentrations substantially exceeded target efficacious concentrations based on a combination of in-vitro and in-vivo pharmacology studies in animals, supporting the potential as a once daily therapy for DME. RZ402 was generally safe and well-tolerated, including at higher doses than previously tested in the single ascending dose (SAD) study. There were no serious adverse events, adverse drug reactions, or identified risks.

About Rezolute, Inc.

Rezolute strives to disrupt current treatment paradigms by developing transformative therapies for devastating rare and chronic metabolic diseases. Its novel therapies hold the potential to both significantly improve outcomes and reduce the treatment burden for patients, treating physicians, and the healthcare system. Rezolute is steadfast in its mission to create profound, positive, and lasting impacts on patients' lives. Patient, clinician, and advocate voices are integrated in the Company's drug development process. Rezolute places an emphasis on understanding the patient's lived experiences, enabling the Company to boldly address a range of severe conditions. For more information, visit www.rezolutebio.com.

Forward-Looking Statements

This release, like many written and oral communications presented by Rezolute and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of Rezolute, are generally identified by use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. These forward-looking statements include, but are not limited to and statements regarding PRIME designation and the designation's meaning on the ability of RZ358 to become an effective treatment to congenital HI, the effectiveness or future effectiveness of RZ358 for the treatment of congenital HI, and statements regarding clinical trial timelines for RZ358. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, Rezolute undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made. Important factors that may cause such a difference include any other factors discussed in our filings with the SEC, including the Risk Factors contained in the Rezolute's Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available at the SEC's website at www.sec.gov. You are urged to consider these factors carefully in evaluating the forward-

looking statements in this release and are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement.

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Exhibit 99.2

Rezolute Initiates Phase 3 Clinical Study for RZ358 in Congenital Hyperinsulinism

Company anticipates completing enrollment by the end of 2024 and reporting topline results in mid-year 2025

Redwood City, Calif., December 14, 2023 -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced the initiation of sunRIZE, a pivotal Phase 3 clinical study of RZ358 in patients with congenital hyperinsulinism (cHI). Following country-level regulatory and ethics committee approvals, the first clinical site has now been activated outside the US, allowing for patient screening and enrollment to commence. Additional sites are being activated on a regular basis over the coming weeks and into the beginning of 2024.

The company's progression into Phase 3 was preceded and enabled by a successful Phase 2 trial (the RIZE study), which demonstrated promising results in the treatment of cHI, a serious condition with a tremendous burden on patients and families and a substantial unmet medical need. The current announcement of the Phase 3 start follows the receipt of a priority medicines (PRIME) designation of RZ358 for the treatment of cHI from the European Medicines Agency in October 2023.

“The start of the Phase 3 study marks a significant milestone in the development of RZ358 and exemplifies the tremendous progress of our Company as a whole. The unmet medical need for patients and their families living with cHI is unequivocal, particularly given that the only approved therapy, diazoxide, is unable to work in more than half of patients, or alternatively is associated with significant side effects in those that respond,” remarked Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. “Better therapies are desperately needed, and we look forward to working closely with sites throughout the world to advance patient screening and enrollment in this pivotal study, so as to move one step closer to realizing that goal.”

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 RZ358 in patients with cHI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study will enroll up to 56 participants and be conducted at approximately 20 expert centers in more than a dozen countries around the world, many of which also participated in the Phase 2 RIZE study.

In the main comparator-controlled portion of the study, 48 participants in the age group of 1 year and older will be randomized (2:1) to receive RZ358 at doses of either 5mg/kg (n=16) or 10mg/kg (n=16), or matched placebo (n=16), in double-blind fashion and as add-on to standard of care. In parallel, an additional open-label arm will be conducted in approximately 8 additional participants in the age group of 3 months to 1 year old at a starting dose of 5mg/kg dose, which may be increased to 10 mg/kg as needed. All participants will receive study drug bi-weekly during a 6-week loading period, followed by every 4 weeks during the remainder of a 24-week total pivotal treatment period.

The primary efficacy endpoint over the 24-week pivotal period will be the change in average weekly hypoglycemia events (<70 mg/dL), as measured by point-of-care blood glucose. The key secondary endpoint is the change in average daily percent time in hypoglycemia (<70 mg/dL), as measured by continuous glucose monitor (CGM). Additional secondary endpoints to be evaluated include serious/symptomatic hypoglycemia events and time, hypoglycemia-related hospitalizations, and quality of life outcomes related to hypoglycemia. Following the end of the pivotal treatment period, participants may have the option to enter the open-label extension portion of the study.

About Congenital HI

Congenital HI is the most common cause of recurrent and persistent hypoglycemia in children. Patients with congenital HI typically present with signs or symptoms of hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. In cases of congenital HI that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse congenital HI where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although about half of these children will continue to have hypoglycemia and require medical treatment for congenital HI.

About RZ358

RZ358 is a fully human monoclonal antibody that works downstream from the pancreas and instead binds to a unique allosteric site on insulin receptors in the liver, fat, and muscle. The antibody counteracts the effects of excess insulin binding and activity, thereby correcting hypoglycemia. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital HI and other conditions characterized by excessive insulin activity (hyperinsulinism). Because RZ358 acts downstream from the pancreas, it has the potential to be universally effective at treating congenital HI, regardless of the causative genetic defect, as well as acquired forms of HI such as those mediated by insulinomas and other tumor types. RZ358 received Orphan Drug Designation in the United States and European Union for the treatment of congenital HI, as well as Pediatric Rare Disease Designation in the US. In the Phase 2 RIZE study, participants with cHI ages 2 and older nearly universally achieved significant improvements in hypoglycemia across multiple endpoints, including the primary and key secondary endpoints planned for the sunRIZE study. At doses and exposures that are planned for the Phase 3 study, RZ358 was generally safe and well-tolerated, and resulted in median improvements in hypoglycemia exceeding 80%. Based on the RIZE clinical trial outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, RZ358 was subsequently granted a priority medicines (PRIME) designation for the treatment of cHI by the European Medicines Agency

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