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): May 21, 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 May 21, 2024, Rezolute, Inc. issued a press release to announce positive topline results from a Phase 2 clinic study of RZ402 in 94 patients with diabetic macular edema who are naïve to or have received limited anti-vascular growth factor injections.

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 May 21, 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: May 24, 2024

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

Exhibit 99.1

Rezolute Reports Positive Topline Results from Phase 2 Proof of Concept Study of RZ402 in Patients with Diabetic Macular Edema (DME)

Met primary study endpoints: good safety profile and reduction in central subfield thickness (CST)

First oral therapy to demonstrate reduction in macular edema; supports potential for early disease intervention

Virtual investor event to be held today at 5:30pm ET

REDWOOD CITY, Calif., May 21, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced positive topline results from the Phase 2 clinical study of RZ402 in patients with DME who are naïve to or have received limited anti-vascular growth factor (anti-VEGF) injections.

"The results are monumental for the DME community," said Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology at the Byers Eye Institute, and Professor of Medicine and Professor of Pediatrics at the Stanford University School of Medicine, and a member of Rezolute's Scientific Advisory Board. "I am impressed by the significant reduction in CST in this study across all three dosages as retinal thickness is the key biomarker to determine whether a therapy may offer a potential benefit to patients. These data are very encouraging and are supportive of the potential for a new first-line, non-invasive treatment for DME."

94 participants were enrolled in the U.S. multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week (three month) treatment period.

"I am encouraged to see the initial results of this proof-of-concept study and am enthusiastic about the possibility of an oral therapy to treat DME," said Arshad Khanani, MD, MA, FASRS, Clinical Professor at the Reno School of Medicine, University of Nevada, and Primary Investigator of the study. "Importantly, an oral therapy would afford us the opportunity to address both eyes and intervene much earlier, potentially altering the long-term prognosis for individuals with DME."

"We are very excited about these results and, importantly, would like to thank the patients, the leading retina specialists across the country, and their motivated staff who all made this study possible," said Raj Agrawal, MD, Vice President and Head of Ophthalmological Clinical Development at Rezolute.

Study design and eligibility criteria

- DME patients with mild to moderate non-proliferative diabetic retinopathy (DR)

- Patients must have received no more than three anti-VEGF injections previously (none within eight weeks of randomization)
- CST of ≥320 microns in males and ≥305 microns in females
- Best Corrected Visual Acuity (BCVA) of ≤78 letters on Early Treatment Diabetic Retinopathy Study (ETDRS) assessment
- Eligible participants were randomized equally, to one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg, or a placebo control arm, to receive study drug once daily for 12 weeks, before completing a four-week follow-up

RZ402 met both primary endpoints of change in macular edema (CST) and a good safety profile

- CST improved significantly at all RZ402 dose levels compared to placebo (up to approximately 50 microns; p=0.02)
  - Continued downward trajectory in CST over course of study and at end of treatment
  - No significant difference between RZ402 dose levels, though response was largest at the 200 mg dose
  - Sub-analysis by DME severity (CST ≥400 microns) indicates an improvement of approximately 75 microns at the 200 mg dose
  - CST declined in most patients who received the 200 mg dose of RZ402, including clinically significant improvements from baseline in more than 20% of participants, compared to none in placebo, with high rates of worsening
- RZ402 was safe and well-tolerated
  - Adverse events (AEs) were generally mild and rates were comparable to placebo
  - Three participants experienced serious AEs which were all judged by the Investigator as unrelated to study drug
  - No ocular adverse effects that are typically seen with intravitreal injections
  - Electrocardiograms (ECGs), vitals, and safety labs were unremarkable
- Target concentrations were exceeded at all three dose levels and continue to support once daily oral dosing

Secondary and additional endpoints

- No significant improvements in BCVA compared to placebo
  - In-line with expectations for a study of this duration
  - Observed improvements in CST would predict visual improvements in a longer duration study
- Five RZ402 treated participants at 200 mg (20 percent) experienced a 1-step improvement in Diabetic Retinopathy Severity Score (DRSS) compared to one participant in placebo

The Company plans to present these data and further findings at an upcoming medical conference.

Virtual Investor Event

The Company will host a virtual investor event to review these topline results today at 5:30pm ET. The event will be webcast live and a replay of the webcast will be archived in the Events section of the Company's investor relations website following the event.

Date: Tuesday, May 21st, 5:30pm ET
Webcast: https://event.choruscall.com/mediaframe/webcast.html?webcastid=6VUQj5bb
Dial-in:

- Toll Free: 1-877-270-2148
- International: 1-412-902-6510

About DME

DME is a severe, systemic, vision-threatening complication of diabetic retinopathy (DR) characterized by swelling of the retina and thickening of the macula, the part of the eye that is responsible for high-resolution vision. Anti-VEGF injections into the eye are the current standard of care for DME, requiring continued administration over long periods of time to preserve vision. Due to their invasive route of administration and occasional serious side effects, there is a tendency to delay treatment until later in the disease course, and long-term compliance with eye injection regimens can be difficult for patients. Coupled with inadequate responsiveness in some patients, this leads to overall undertreatment and suboptimal vision outcomes in DME patients. 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.

About RZ402

RZ402 is an oral, small molecule, selective and potent, plasma kallikrein inhibitor (PKI), 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. Topline results from the Phase 2 study of RZ402 in patients with DME demonstrated a significant reduction in central subfield thickness (CST) in the Study Eye at all RZ402 dose levels compared to placebo (up to approximately 50 micron improvement) and was safe and well-tolerated.

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 significantly improve outcomes and to reduce the treatment burden for patients, treating physicians and the healthcare system. Rezolute is steadfast in its mission to create a profound, positive and lasting impact on the lives of patients. 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," "prove," "potential," "seek," "strive," "try," or future or conditional verbs such as "predict," "could," "may," "likely," "should," "will," "would," or similar expressions. These forward-looking statements include, but are not limited to statements regarding the RZ402 study, the ability of RZ402 to become an effective treatment for diabetic macular edema, the effectiveness or future effectiveness of RZ402 to become an effective treatment for diabetic macular edema, and statements regarding clinical trial timelines for RZ402. 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.

Contacts:

Rezolute, Inc.
Christen Baglaneas
cbaglaneas@rezolutebio.com
508-272-6717

LHA Investor Relations
Tirth T. Patel
tpatel@lhai.com
212-201-6614
