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 15, 2022

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 15, 2022, Rezolute, Inc. issued a press release announcing the initiation of a Phase 2 Study of RZ402 in Patients with Diabetic Macular Edema. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release, dated December 15, 2022
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 15, 2022

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

Exhibit 99.1

Rezolute Announces Initiation of a Phase 2 Study of RZ402 in Patients with Diabetic Macular Edema

RZ402 is an oral therapy being developed as a potential alternative to invasive and suboptimal injections into the eye

REDWOOD CITY, Calif., Dec. 15, 2022 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to shift the treatment paradigms of devastating metabolic diseases, today announced that the Company has initiated a Phase 2 proof-of-concept study for RZ402, a plasma kallikrein inhibitor (PKI) being developed as an oral therapy for the treatment of Diabetic Macular Edema (DME). The current standard of care for DME is anti-vascular growth factor (anti-VEGF) injections into the eye, requiring repeated administration over recurring periods of time to preserve vision, with significant treatment burden and occasional serious side effects. The invasive route of administration, coupled with inadequate responsiveness in some patients, leads to overall undertreatment and suboptimal vision outcomes in DME patients.

“The initiation of this Phase 2 study is an important milestone in our mission to address the serious unmet need in the current DME treatment paradigm,” said Raj Agrawal, M.D., Vice President, and Head of Ophthalmological Clinical Development at Rezolute. “By targeting an alternative pathway and route of administration to the current standard of care, we believe that orally-administered RZ402 has the potential to be a less burdensome and more beneficial treatment option for all patients suffering with DME, including the approximately 50% of patients that don’t adequately respond to anti-VEGFs.”

“We believe that RZ402 represents the potential for a significant change in the treatment paradigm of DME,” said Brian Roberts, M.D., Chief Medical Officer at Rezolute. “By targeting this microvascular diabetes complication with an oral-systemic PKI, analogous to the management of other diabetes complications, RZ402 has the potential to improve overall clinical outcomes by driving earlier treatment intervention and preventing disease progression and vision loss for patients with DME. We look forward to building upon the positive data generated in our Phase 1b trial and remain excited by the broad clinical potential of RZ402 to more effectively treat diseases associated with excessive kallikrein-kinin activity.”

The Phase 2 study is a multi-center, randomized, double-masked, placebo-controlled, parallel-arm study to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as monotherapy over a 12-week treatment period in participants with DME who are naïve to or have received limited anti-VEGF injections. The study population will include DME patients with mild to moderate Non-Proliferative Diabetic Retinopathy (NPDR), Central Subfield Thickness (CST) of ≥320 µm (or corresponding values), and Best-Corrected Visual Acuity (BCVA) of ≤78 Early Treatment Diabetic Retinopathy Study (ETDRS) letters (≤20/25 on Snellen chart). Patients who have previously received more than three anti-VEGF injections prior to the study will be excluded.

Eligible participants will be randomized equally, to one of three RZ402 active treatment arms at doses of 50, 200, and 400 mg, or a placebo control arm, and will receive study drug once daily for 12 weeks, before completing a four-week follow-up. The study is expected to enroll approximately 100 patients overall, across approximately 25 investigational sites in the United States. The principal endpoints of the trial include the change in CST, as measured by Spectral Domain Ocular Coherence Tomography (SD-OCT), the change in visual acuity by ETDRS scale, the repeat dose pharmacokinetics of RZ402 in patients with DME, and the safety and tolerability of RZ402.

About Diabetic Macular Edema (DME)
Diabetic retinopathy (DR) affects approximately one third of adults with diabetes and is the leading cause of vision loss in the working age population. DME is a severe vision-threatening complication of 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-vascular growth factor (anti-VEGF) injections into the eye are the current standard of care for DME, requiring repeated administration over recurring 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.

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 formation of kallikrein, RZ402 is designed to block downstream bradykinin production and the pro-inflammatory, pro-coagulant and fluid leaking contact-activation cascade.

Results from the Phase 1b multiple ascending dose (MAD) study showed that RZ402 was readily bioavailable with dose-dependent increases in systemic exposures. Results at both peak and 24-hour trough substantially exceeded target concentrations based on a combination of in-vitro and in-vivo profiling. 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.

RZ402 has been shown to reduce and prevent retinal vascular leakage in animal models by 80-90%.

About the Contact Activation Kallikrein-Kinin System
The contact-activation kallikrein-kinin system promotes increased vascular permeability and inflammation via key downstream mediators, including bradykinin, and activation of the intrinsic pathway of coagulation. Pathophysiologic upregulation of this system has been linked to a variety of diseases which are characterized by vascular dysfunction, including diabetic macular edema.

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, the treating physician, and the healthcare system. Patient, clinician, and advocate voices are integrated in the Company's drug development process, enabling Rezolute to boldly address a range of severe conditions. Rezolute is steadfast in its mission to create profound, positive, and lasting impact on patients' lives. The Company's lead clinical asset, RZ358, is in late-stage development for the treatment of congenital hyperinsulinism, a rare pediatric endocrine disorder. Rezolute is also developing RZ402, an orally available plasma kallikrein inhibitor, for the treatment of diabetic macular edema. For more information, visit www.rezolutebio.com or follow us on Twitter.

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. 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 Rezolute's 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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