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): August 10, 2021

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

Nevada	000-54495	27-3440894
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

201 Redwood Shores Pkwy, Suite 315, 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 August 10, 2021, Rezolute, Inc. ("Rezolute") announced the initiation dosage in a Phase 1b multiple-ascending dose study of RZ402 and the appointment of Dr. Rajat Agrawal as Vice President, Clinical Development to lead the RZ402 clinical development program.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit	Description
99.1	Press release dated August 10, 2021

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: August 10, 2021

By: */s/ Nevan Elam*
Nevan Elam

Chief Executive Officer

Exhibit 99.1

Rezolute Announces initiation of multiple-ascending dose study of RZ402,
Rezolute's oral PKI for treatment of DME

REDWOOD CITY, Calif., August 10, 2021 (GLOBE NEWSWIRE) – **Rezolute, Inc.** (Nasdaq: RZLT), a clinical-stage biopharmaceutical company developing transformative therapies for metabolic diseases associated with chronic glucose imbalance, today announced that the Company has initiated dosing in a Phase 1b multiple-ascending dose study of RZ402, Rezolute's investigational oral plasma kallikrein inhibitor (PKI) for the treatment of diabetic macular edema (DME). Rezolute also announced the appointment of ophthalmology expert and key opinion leader, Dr. Rajat Agrawal, MD, MS, as Vice President, Clinical Development to lead the RZ402 clinical development program.

"The Phase 1b study will evaluate the safety of RZ402 in healthy volunteers and inform the dose range selection in the phase 2 proof-of-concept study, planned for next year," said Brian Roberts, Senior Vice President and Head of Clinical Development at Rezolute. "There is a significant unmet need for new ways to treat DME, due to the high treatment burden of current standard of care involving anti-VEGF injections into the eye. With Dr. Agrawal's expertise as a retinal specialist and his drug development expertise in the therapeutic area, we're looking forward to developing a more convenient oral therapy with the potential to prevent and treat the vision loss commonly experienced by patients with diabetes.".

Dr. Agrawal brings over three decades of experience across both the clinical and commercial spectrums, having practiced as an ophthalmology and retina specialist for more than 25 years, and having served as an executive at other clinical-stage biotechnology companies. Dr. Agrawal also founded Retina Global, an international nonprofit focused on sustainable solutions to retinal disease management globally, aimed at evaluating patients, providing medical and surgical treatment and training local ophthalmologists.

"It is a privilege to have the opportunity to work on a program with the potential to have such a profound and positive impact on patients' lives," said Dr. Agrawal. "I regularly witness the unfortunate impact of retinal diseases on patients, and Rezolute's innovative approach would be a huge step forward for the DME community. I am honored to be joining this team, and I look forward applying my expertise to the further advancement of the RZ402 program."

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 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.

About RZ402 and 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.

RZ402 is a selective and potent plasma kallikrein inhibitor (PKI) being developed as a potential oral therapy for the chronic treatment of diabetic macular edema (DME). By inhibiting the formation of kallikrein, RZ402 is designed to block downstream bradykinin production and the pro-inflammatory, pro-coagulant, and fluid-leakage contact-activation cascade.

Earlier this year, we reported topline results from the first-in-human Phase 1a single-ascending dose study, demonstrating that RZ402 was generally safe and well-tolerated at all doses tested, without dose-limiting toxicities. Rezolute also presented at the 2021 Stanford Retina Innovation Summit last month discussing RZ402 and targeting DME with kallikrein inhibitors.

About RZ402-102

RZ402-102 is a Phase 1, single-center, randomized, double-blind, placebo-controlled, multiple ascending dose study in healthy adult volunteers. The objectives of the study are to characterize the repeat-dose safety profile (including maximum tolerated dose) and pharmacokinetics of RZ402 administered as daily oral doses for 2 weeks. The study will be conducted in a minimum of 40 subjects in four planned sequential ascending dose-level cohorts comprising ten subjects per cohort. Within each dose cohort, subjects will be randomized in an 8:2 ratio to receive either RZ402 oral solution or matched placebo. Participants will remain in-clinic throughout the 2-week dosing period for serial pharmacokinetic and safety assessments, before completing an outpatient follow-up visit at study day 28. Blood biomarkers of target engagement (kallikrein activity) will be explored as a systemic surrogate for DME, using a precedent from studies of kallikrein inhibitors in a systemic vascular leakage syndrome (hereditary angioedema). Dose advancement will proceed in staggered fashion every 3 weeks as appropriate, following blinded reviews of data from the preceding cohort(s). The study is expected to conclude with results in the first quarter of 2022.

About Rezolute, Inc.

Rezolute is developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company's lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (CHI), a rare pediatric endocrine disorder. The Company 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, Inc. 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 the Company, 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.

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