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): October 19, 2021(October 13, 2021)

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.)**

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.

Rezolute, Inc. ("Rezolute") presented information about RZ402 Phase 1 single dose study at the 2021 ASRS meeting.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit	Description
99.1	Abstract presented at 2021 ASRS meeting

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: October 19, 2021

By: */s/ Nevan Elam*
Nevan Elam

Chief Executive Officer

Exhibit 99.1

ABSTRACT FOR THE 2021 ASRS MEETING

Title:

A Phase 1 Single Dose Study of RZ402: a Novel Orally Administered Plasma Kallikrein Inhibitor to Target Diabetic Macular Edema

Presenters:

Robert Bhisitkul, MD, PhD[1], Quan Dong Nguyen, MD, MSc[2], Brian Roberts, MD[3], Rajat Agrawal, MD, MS[3]

1. Department of Ophthalmology, University of California, San Francisco, CA
2. Byers Eye Institute, Stanford University, Palo Alto, CA
3. Rezolute, Inc, Redwood City, CA

Background:

The plasma kallikrein-kinin system (KKS) promotes vascular inflammation and permeability through bradykinin and related mediators, and is implicated in a number of systemic and local vascular diseases. Plasma kallikrein inhibitors (PKI) are already approved for hereditary angioedema, a systemic vascular leakage syndrome. The KKS is also up-activated in retinal microvascular diseases, and studies have shown it to be both a VEGF-dependent and - independent mediator of DME. Therefore, oral-systemic PKIs offer a potential novel and convenient approach for the treatment of diabetic retinopathy (DR) and/or macular edema (DME). RZ402 is a novel, orally administered, potent and selective plasma kallikrein inhibitor (PKI) which has been shown to reduce retinal vascular leakage in various animal models of DME. A phase 1, first-in-human study was conducted to assess the safety and pharmacokinetics (systemic exposure) of oral RZ402 in a clinical development program for the treatment of DME.

Methods:

A phase 1 randomized, double-masked, placebo-controlled, single-ascending-dose study of RZ402 oral solution in 30 healthy adult male and female subjects was conducted.

Three sequential ascending dose cohorts of 10 subjects each were enrolled, with each cohort receiving single oral doses of RZ402 (or matched placebo in 8:2 fashion) at dose levels of 25-mg 100-mg, and 250-mg. Safety assessments included systemic and ophthalmic evaluations. Serial plasma RZ402 concentrations by LC/MS/MS supported the pharmacokinetic evaluation.

Results:

All 30 subjects completed the study with no discontinuations andsingle doses of RZ402 were generally safe and well tolerated across all dose levels. Overall, 13 subjects (54%) who received RZ402 experienced a total of 18 adverse events (AEs), compared to 2 subjects (33%; 5 AEs) who received placebo. A significant number of the AEs in subjects who received RZ402 were procedure-related (ECG electrode irritation), with only 3 AEs (diarrhea, nausea and headache; all grade 1/mild) in 3 subjects judged by the Investigator as possibly related to the study drug. There was no grade 2 or 3 (severe) or higher AEs nor any serious AEs (SAEs). No clinically meaningful changes in laboratory values, vital signs, or ECG results were observed, and physical and ophthalmic examinations were unremarkable. There were no adverse drug reactions or observed dose-limiting toxicities. Dose-dependent increases in RZ402 concentrations were observed with peak levels at 3 to 4 hours after dose (median) and elimination half-life at 20.2 to 25.6 hours (geometric mean) across the dose groups. Durable and pharmacologically relevant concentrations of RZ402 were observed throughout the intended 24-hour dosing interval.

Conclusion:

RZ402, a novel, orally administered PKI was demonstrated to have a good systemic and ocular safety profile and produced effective serum levels over 24 hours that support a once-a-day oral regimen as a potential treatment for patients with DME. Further clinical studies are warranted and are ongoing.
