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 3, 2020

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

Delaware	**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 December 3, 2020, the Company issued a press release reporting the FDA's clearance of the Company's Investigational New Drug application for RZ402. A copy of the press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

The information set forth in this Item 7.01, including Exhibit 99.1, is being furnished and 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 liabilities of that section. The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description**
99.1	Press Release dated December 3, 2020.

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 3, 2020

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

FDA CLEARS REZOLUTE'S IND APPLICATION FOR RZ402

RZ402 IS AN ORALLY AVAILABLE PLASMA KALLIKREIN INHIBITOR IN DEVELOPMENT FOR THE TREATMENT OF DIABETIC MACULAR EDEMA

REDWOOD CITY, Calif., Dec. 03, 2020 (GLOBE NEWSWIRE) --**Rezolute, Inc.** (Nasdaq:RZLT), focused on advancing therapies for rare, metabolic and life-threatening diseases, announced today that the U.S. Food and Drug Administration (FDA) has cleared an Investigational New Drug (IND) application for RZ402, an orally available plasma kallikrein inhibitor, which is in development for the treatment of diabetic macular edema (DME). The Company expects to initiate a Phase 1 first-in-human clinical study with RZ402 in the first quarter of 2021.

RZ402, by inhibiting the formation of kallikrein, blocks the pro-inflammatory, pro-coagulant, and fluid-leakage cascade which is triggered by up-activation of the contact activation system in the setting of DME and other vascular-mediated diseases. As a result, it has been shown to reduce retinal inflammation and retinal vascular leakage of DME by more than 80% in both preventative and treatment models in rodents. Preclinical studies have also shown an excellent safety profile for RZ402 in both single- and repeat-dose settings at a range of doses. These data, taken together with oral bioavailability and exposure-time profile in canines and non-human primates showing target concentrations are achieved at clinically relevant oral doses, demonstrate the potential of RZ402 as a once-daily oral treatment option for DME.

Brian Roberts, M.D., Rezolute's head of research and clinical development, commented, "The positive data we have collected from our animal studies highlight RZ402's potential to address a glaring unmet need in the treatment of diabetic macular edema. Although the emergence of the anti-VEGF therapies has resulted in significant progress in the management of DME, a high percentage of patients do not adequately respond and/or do not tolerate this class of therapies. They have the obvious shortcoming of requiring frequent, burdensome intravitreal injections directly into the eye, often leading to delayed initiation or otherwise sub-optimal administration frequency. As a result, real-world vision outcomes also tend to be suboptimal. Based on animal studies demonstrating safety and efficacy at clinically relevant target exposures achieved with oral administration, we believe that once-daily oral administration of RZ402 has the potential to address these shortcomings. The submission and successful clearance of this IND is a key step towards evaluating RZ402's potential as an oral therapy for DME, and we are looking forward to the upcoming initiation of clinical studies in the first quarter of next year."

About Diabetic Macular Edema
Diabetic retinopathy (DR) affects approximately one third of adults with diabetes and can put patients at risk for vision loss. Consistently high blood sugar levels can cause DR, which is characterized by damage to the blood vessels in the eye and fluid leakage into the retina. Diabetic macular edema (DME) is a vision-threatening severe complication of DR marked by progressive vision loss and the potential for blindness. The accumulation of fluid leads to swelling and retinal thickening in the area of the macula, the part of the retina responsible for sharp, straight-ahead vision. The current standard of care for DME are the anti-VEGF therapies, which require repeated injections into the eye over long periods of time in order to preserve vision, and have an inadequate effectiveness and/or safety profile in a significant portion of patients**.** Compliance with these regimens can be difficult for patients, which in addition to inadequate responsiveness in a high percentage of patients, leads to overall undertreatment and suboptimal vision outcomes in the DME patient population.

About Rezolute, Inc.
Rezolute is advancing targeted therapies for rare, metabolic, and life-threatening diseases. Its lead clinical asset, RZ358, is in Phase 2b development as a potential treatment for congenital HI, a rare pediatric endocrine disorder. Its pipeline also includes RZ402, an IND-ready orally available plasma kallikrein inhibitor which is staged to transition into clinical development 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.

Media Contact
Amy Jobe, Ph.D.
LifeSci Communications
+1 315 879 8192
ajobe@lifescicomms.com

Investor Contact
Corey Davis, Ph.D.
LifeSci Advisors
+1 212 915 2577
cdavis@lifesciadvisors.com