

**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): June 16, 2023**

**REZOLUTE, INC.**

(Exact Name of Registrant as Specified in Charter)

**Nevada**  
(State or Other Jurisdiction  
of Incorporation)

**001-39683**  
(Commission  
File Number)

**27-3440894**  
(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
<b>Common Stock, par value \$0.001 per share</b>	<b>RZLT</b>	<b>Nasdaq Capital Market</b>

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. (the "Company") maintains an expanded access program ("EAP") for the purpose of making the Company's antibody therapy, RZ358, available on a compassionate use basis when all other therapeutic options have been exhausted and an individual's hypoglycemia is unmanageable. In Q4 2022, the Company received and approved an EAP request from Dr. Mary Elizabeth Patti, Director of the Hypoglycemia Clinic at the Harvard Medical School and Beth Israel Medical Center-affiliated Joslin Diabetes Center, for a patient with intractable hypoglycemia caused by a metastatic insulin-producing neuroendocrine tumor ("insulinoma"). Dr. Patti received US Food and Drug Administration approval and local institutional review board approval for an individual new drug application to treat the patient with RZ358. The patient began receiving the antibody therapy in Q4 2022 and continues to receive it at Dr. Patti's direction. Dr. Patti has reported that the patient has safely achieved a substantial benefit in the correction of hypoglycemia and associated quality of life following the continued administration of RZ358.

Dr. Patti's use of RZ358 for a patient that is suffering with insulinoma marks the first time that the Company has provided its therapy for use in this indication. Dr. Patti submitted an abstract related to this patient's experience as a case-study to the 105<sup>th</sup> Annual Scientific Meetings of the Endocrine Society. The study, "Treatment of Severe Refractory Hypoglycemia Due to Malignant Insulinoma With A Novel Anti-insulin Receptor Antibody", was accepted as a late-breaking abstract and was presented by Dr. Patti in poster form on Friday, June 16, 2023. The original abstract will be published in a supplemental issue of the Journal of the Endocrine Society. A link to the poster presentation of the abstract is available in the News and Publication section of Rezolute's website.

**Cautionary Note Regarding Forward-Looking Statements**

Certain statements made herein that are not historical facts are forward-looking statements for purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995. Forward looking statements generally are accompanied by words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "would," "plan," "predict," "potential," "seem," "seek," "future," "outlook" and similar expressions that predict or indicate future events or trends or that

are not statements of historical matters. These forward-looking statements include, but are not limited to, statements regarding future events and results, the development and efficacy of RZ358, the effectiveness of RZ358 and any perceived benefits of RZ358 based on Dr. Patti's abstract.

These statements are based on the current expectations of the Company and are not predictions of actual performance, and are not intended to serve as, and must not be relied on, by any investor as a guarantee, prediction, definitive statement, or an assurance, of fact or probability. These statements are only current predictions or expectations, and are subject to known and unknown risks, uncertainties and other factors which may be beyond our control. Actual events and circumstances are difficult or impossible to predict, and these risks and uncertainties may cause our or our industry's results, performance, or achievements to be materially different from those anticipated by these forward-looking statements. A further description of risks and uncertainties can be found in the sections captioned "Risk Factors" in our most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q, and other filings with or submissions to, the U.S. Securities and Exchange Commission, which are available at <https://www.sec.gov/>. Except as otherwise required by law, the Company disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events, or circumstances or otherwise.

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#### 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: June 20, 2023

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

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