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 11, 2023

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 October 11, 2023, Rezolute, Inc. (the "Company") issued a press release announcing an update on RZ358. A copy of the press release is attached as Exhibit 99 to this Current Report on Form 8-K and is hereby incorporated by reference.

The information in Item 7.01 of this Current Report on Form 8-K, including the attached Exhibit 99 is being furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for any purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such Section, and shall not be deemed to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit	Description
99	Press Release dated October 11, 2023
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: October 13, 2023

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

Exhibit 99

Rezolute Announces Further Evidence of RZ358's Efficacy in Tumor-Mediated Hyperinsulinism

Redwood City, Calif., October 11, 2023 -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced results following administration of RZ358 to a patient with refractory hypoglycemia due to tumor-mediated hyperinsulinism (tmHI) on a compassionate-use basis, under its expanded access program (EAP).

The Company previously reported on the successful use of RZ358 for a patient with refractory hypoglycemia due to metastatic insulinoma, which has since been published in a recent edition of the *New England Journal of Medicine* (389;8). As a result of that publication, the Company recently received and granted a request from a physician-investigator who had FDA approval to use RZ358 for a patient with refractory hypoglycemia due to a metastatic, insulin-secreting cervical cancer. The patient began receiving treatment with RZ358 in September 2023, which resulted in resolution of her hypoglycemia and enabled her to be discharged from the hospital to resume cancer-directed therapy while continuing to receive RZ358 to control hypoglycemia. Notably, the individual with metastatic insulinoma has remained on RZ358 for nearly a year.

"Not only is it gratifying to be able to provide RZ358 to patients who desperately need new therapies for hyperinsulinism, we are extremely encouraged by the very favorable glycemic outcomes achieved in these two patients with different types of tumor-mediated HI," remarked Brian Roberts, MD, Chief Medical Officer at Rezolute. "We believe that this provides further validation of our long-held view of hyperinsulinism as a group of related conditions, and RZ358 as a potential universal treatment for any of the various causes of hyperinsulinism, whether congenital, induced by gastric bypass, or mediated by tumors. We are in the process of evaluating next steps to develop RZ358 in these additional indications."

About Tumor-Mediated Hyperinsulinism

Hypoglycemia from tmHI may be caused by a variety of benign and malignant pancreatic neuroendocrine tumors (insulinomas), other non-pancreatic insulin-producing cancers, or sometimes by non-islet cancers that make other substances with insulin-like effects. The prevalence of non-surgical and refractory forms of these conditions is estimated at approximately 2,000 individuals in the US with no adequate available treatments, and therefore the Company believes that it represents another rare disease with a substantial unmet need.

About RZ358

RZ358 is a fully human monoclonal antibody that works downstream from the pancreas and instead binds to a unique allosteric site on insulin receptors in the liver, fat, and muscle. The antibody counteracts the effects of elevated insulin in the body by modulating insulin's binding, signaling, and activity to restore glucose levels to a normal range. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital hyperinsulinism (cHI) and other conditions characterized by excessive insulin levels. Because RZ358 acts downstream from the pancreas, it has the potential to be universally effective at treating cHI, regardless of the causative genetic defect, as well as acquired forms of HI such as those mediated by insulinomas and other tumor types. RZ358 received Orphan Drug Designation in the United States and European Union for the treatment of cHI, as well as Pediatric Rare Disease Designation in the US.

The Company's Phase 2b trial (RIZE) of RZ358 in patients with cHI, demonstrated that RZ358 was generally safe and well-tolerated, as well as highly effective in correcting hypoglycemia, in participants who were failing available standard of care therapies. The Company is on track to initiate a pivotal Phase 3 trial of RZ358 (sunRIZE) outside the US in individuals three months of age and older in Q4 2023. The addressable market for cHI is estimated to be approximately 3,500 patients in the US and 10,000 patients overall in addressable markets.

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, treating physicians, and the healthcare system. Rezolute is steadfast in its mission to create profound, positive, and lasting impacts on patients' lives. Patient, clinician, and advocate voices are integrated in the Company's drug development process. Rezolute places an emphasis on understanding the patient's lived experiences, enabling the Company to boldly address a range of severe conditions. 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.

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. These forward-looking statements include, but are not limited to and statements regarding the effectiveness or future effectiveness of RZ358 for the treatment of HI, statements regarding RZ358 and the extent to which it could be an effective treatment for various causes of HI and statements regarding clinical trial timelines for RZ358. 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 our 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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