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): April 23, 2024

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 April 23, 2024, Rezolute, Inc. issued a press release to announce that Paul Thornton, M.D., will present the results of the Rezolute, Inc. Phase 2 RIZE study at the Pediatric Endocrine Society Annual Meeting, to be held May 2-5, 2024 at the Sheraton Grand Chicago Riverwalk.

The information in this Current Report on Form 8-K, including Exhibit 99.1, 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 liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 23, 2024
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: April 25, 2024

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

Phase 2 RIZE Study Sub-Analyses to be Presented at the 2024 Pediatric Endocrine Society Annual Meeting

REDWOOD CITY, Calif., April 23, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced that a poster titled "An Analysis of Overnight Hypoglycemia in Patients with Congenital Hyperinsulinism: Results from the RZ358-606 (RIZE) Study" will be presented at the Pediatric Endocrine Society (PES) Annual Meeting, to be held May 2-5, 2024 at the Sheraton Grand Chicago Riverwalk.

Paul Thornton, M.D., a Pediatric Endocrinologist with expertise in congenital HI, will present the poster, which details findings from the Company's Phase 2 RIZE study evaluating the treatment of congenital hyperinsulinism (HI) with RZ358 in pediatric patients. While primary and key secondary glycemic endpoints (weekly events and daily percent time) from the RZ358-606 (RIZE) study have been previously reported, the current sub-analyses highlight the benefits of RZ358 during the vulnerable overnight fasting period, utilizing continuous glucose monitor (CGM) to evaluate average time in hypoglycemia (<70 mg/kg) and average glucose levels overnight. These and previously reported results, including improvements in overall hypoglycemia events and time of up to ~90% at the top doses, suggest that RZ358 has the potential to be a safe and effective therapy to treat all forms of congenital HI. A Phase 3 study is currently underway.

Presentation Details
Date: Saturday, May 4, 2024
Time: 12:15 p.m. local time
Abstract ID: 6790

For more information on the conference presentation schedule and to view the poster abstract, please visit the PES Annual Meetingwebsite.

About Congenital Hyperinsulinism

Congenital hyperinsulinism (HI) is the most common cause of recurrent and persistent hypoglycemia in children. Patients with congenital HI typically present with signs or symptoms of hypoglycemia within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Additionally, recurrent, or cumulative, hypoglycemia can lead to progressive and irreversible damage over time, including serious and devastating brain injury, seizures, neuro-developmental problems, feeding difficulties, and significant impact on patient and family quality of life. In cases of congenital HI that are unresponsive to medical management, surgical removal of the pancreas may be required. In those with diffuse congenital HI where the whole pancreas is affected, a near-total pancreatectomy can be undertaken, although about half of these children will continue to have hypoglycemia and require medical treatment for congenital HI.

About RZ358

RZ358 is a fully human monoclonal antibody that works downstream from the pancreas and other sources of insulin or related paraneoplastic substances, and instead binds to a unique allosteric site on insulin receptors at target tissues such as liver, fat and muscle. The antibody counteracts excess insulin receptor activation by insulin and related effector substances (such as IGF-2), thereby improving hypoglycemia. Because RZ358 acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to congenital HI, regardless of the causative genetic defect, as well as acquired forms of HI such as those mediated by insulinomas (ICTs) and other tumor types (NICTs).

In the Phase 2 RIZE study in patients with congenital HI ages two and older, nearly all participants achieved significant improvement in hypoglycemia across multiple endpoints, including the primary and key secondary endpoints planned for the sunRIZE study. At doses and exposures that are planned for sunRIZE, RZ358 was generally safe and well-tolerated, and resulted in median improvements in hypoglycemia of up to ~90%. Based on the RIZE clinical trial outcomes and the evidence of benefit in this serious condition with substantial unmet medical need, RZ358 was subsequently granted a priority medicines (PRIME) designation by the European Medicines Agency (EMA) and an Innovation Passport designation by the U.K. Innovative Licensing and Access Pathway (ILAP) Steering Group for the treatment of congenital HI. RZ358 also received orphan drugand pediatric rare disease designation in the U.S., and orphan drug designation in the European Union for the treatment of Insulinoma, the primary cause of ICTH.

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 significantly improve outcomes and to reduce the treatment burden for patients, treating physicians and the healthcare system. Rezolute is steadfast in its mission to create a profound, positive and lasting impact on the lives of patients. 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. 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 statements regarding priority medicines (PRIME) designation, the Innovation Passport designation, the RIZE study, the sunRIZE study, the RZ358 Expanded Access Program, the ability of RZ358 to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of RZ358 for the treatment of congenital hyperinsulinism, 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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