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): March 23, 2022

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.

On March 23, 2022, Rezolute, Inc. issued a press release announcing positive results from its Phase 2b RIZE clinical study of RZ358. A copy of this press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release, dated March 23, 2022
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

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: March 23, 2022

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated March 23, 2022
104	Cover Page Interactive Data File (embedded as Inline XBRL document)

Exhibit 99.1

Rezolute Announces Positive Results from the Phase 2b RIZE Study of RZ358 in Congenital Hyperinsulinism

--The RIZE study demonstrated highly significant improvements in hypoglycemia and good safety and tolerability

Results to be presented in an oral presentation at a medical congress in 2Q 2022

REDWOOD CITY, Calif., March 23, 2022 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to disrupt current treatment paradigms for devastating metabolic diseases, today announced positive data from its Phase 2b RIZE study of RZ358. The data demonstrated the safety and tolerability of RZ358 in patients with congenital hyperinsulinism, as well as highly significant improvements in hypoglycemia. The RIZE study results will be presented in an oral presentation at an upcoming medical congress in 2Q 2022, followed by a conference call hosted by the Company to discuss the data.

“We are very encouraged by the results and are looking forward to moving the program into Phase 3,” said Nevan Charles Elam, CEO and Founder of Rezolute. Mr. Elam continued, “We are very grateful to the patients, their families, patient advocacy organizations, and the investigators who participated in this study. I also appreciate the tremendous dedication of the Rezolute team, who are mission driven to develop an innovative treatment option for this debilitating condition.”

About Congenital Hyperinsulinism (HI)

Congenital HI is the most common cause of recurrent and persistent hypoglycemia in children. It typically presents early in life, with about 60% of infants with congenital HI experiencing 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. The two most-commonly used long-term medications, diazoxide and somatostatin analogs, are not Food and Drug Administration (FDA) approved for all forms of this condition and often are ineffective or have intolerable side effects. 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 is undertaken, but still about half of these children will continue to have hypoglycemia and require medical treatment for congenital HI.

About The RIZE Study

RIZE is a Phase 2b, multicenter, open label, repeat-dose study, designed to assess the safety and tolerability, pharmacokinetics, and glycemic efficacy of RZ358 administered bi-monthly for 8 weeks in patients with congenital hyperinsulinism whose hypoglycemia was not adequately controlled on standard of care therapies. A total of 23 patients participated in the study in four sequential dosing cohorts ranging from 3 mg/kg to 9 mg/kg. The effects of RZ358 on hypoglycemia were assessed by continuous glucose monitor (hypoglycemia time) and glucometer self-monitored blood glucose (hypoglycemia events).

About RZ358
RZ358 is a human monoclonal antibody that binds to a unique site (allosteric) on insulin receptors in the liver, fat, and muscle. The antibody counteracts the effects of elevated insulin in the body by modifying insulin's binding, signaling, and activity to maintain glucose levels in a normal range. Rezolute believes that RZ358 is ideally suited as a potential therapy for congenital hyperinsulinism (HI) and other conditions characterized by excessive insulin levels. As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating congenital HI caused by any of the underlying genetic defects.

RZ358 received Orphan Drug Designation in the United States and European Union as well as Pediatric Rare Disease Designation in the US.

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, the treating physician, and the healthcare system. Patient, clinician, and advocate voices are integrated in the Company’s drug development process, enabling Rezolute to boldly address a range of severe conditions. Rezolute is steadfast in its mission to create profound, positive, and lasting impact on patients’ lives. The Company’s lead clinical asset, RZ358, is in late-stage development for the treatment of congenital hyperinsulinism (HI), 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 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.

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