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): September 23, 2021 (September 22, 2021)

REZOLUTE, INC.

(Exact Name of Registrant as Specified in Charter)

Nevada	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 September 22, 2021, Rezolute, Inc. ("Rezolute") presented results from two-week natural history study in Congenital Hyperinsulinism patients on standard of care therapies at ESPE 2021.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit	Description
99.1	Press release dated September 22, 2021

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: September 23, 2021

By: */s/ Nevan Elam*

Nevan Elam

Chief Executive Officer

Rezolute Presents Results from Two-Week Natural History Study in Congenital Hyperinsulinism Patients on Standard of Care Therapies at ESPE 2021

Continuous glucose monitoring reveals undertreated hypoglycemia in patients with congenital hyperinsulinism

RZ358, a monoclonal antibody in Phase 2b development, has normalized blood glucose levels in prior studies

REDWOOD CITY, Calif., September 22, 2021 (GLOBE NEWSWIRE) – **Rezolute, Inc.** (Nasdaq: RZLT), a clinical-stage biopharmaceutical company developing transformative therapies for metabolic diseases associated with chronic glucose imbalance, today presented results from a natural history study designed to quantify the extent of hypoglycemia in congenital hyperinsulinism (HI) patients on standard of care therapies. The results (E-Poster #P2-234) were presented at the European Society for Paediatric Endocrinology 2021, held virtually September 22-26.

The two-week observational study was conducted in 22 patients ages two years old and older with HI of various genetic causes, 15 of whom were on at least one standard of care therapy, including diazoxide (50% of the patients) and octreotide (18% of the patients). The remaining patients were managed by other means (tube feeds and/or diet). Glucose control was evaluated by continuous glucose monitors (CGM) for at least two weeks.

Study Results

- The mean time in hypoglycemia (±SD, % of monitored time) as measured by CGM (< 70mg/dL) for all participants was 1165 (±164, 11.6%) and 1101 (±152, 10.9%) minutes in weeks 1 and 2, respectively. This included 115 (±36, 0.9%) and 91 (±26, 1.1%) minutes of severe hypoglycemia (<50 mg/dL).
- A 2 to 6 year-old subgroup (n=9) experienced a mean hypoglycemia duration of 1445 (±161,14.3%) and 1376 (±147, 13.7%) minutes in weeks 1 and 2, respectively with 131 (±36, 1.3%) and 146 (±36, 1.5%) minutes of severe hypoglycemia.
- The results equate to an average of over 2.5 hours per day spent in hypoglycemia for all participants, and nearly 3.5 hours per day for those between 2 and 6 years old.
- Notably, patients currently on standard of care therapies experienced a similar magnitude of hypoglycemia.

Current Pediatric Endocrine Society management guidelines recommend maintenance of blood glucose > 70 mg/dL, and consensus guidelines for diabetes hypoglycemia management recommend targeting less than 4% time in the hypoglycemic range (< 70 mg/dL) by CGM. As measured by CGM in this observational study, patients with congenital HI on available standard of care therapies experienced substantial periods of hypoglycemia, leaving them outside of the recommended blood glucose management guidelines.

“Cumulative hypoglycemia places patients with congenital HI at risk for adverse clinical outcomes, including developmental delays and permanent neurologic damage,” said Davelyn Hood, M.D., Director, Scientific and Patient Affairs at Rezolute. “This natural history study highlighted the extended periods of hypoglycemia regularly experienced by vulnerable pediatric and adult congenital HI patients on currently available therapies, at levels more than three times the magnitude than is recommended for the management of hypoglycemia in diabetes. These results further validate the urgent need to develop innovative new treatments for congenital HI to more effectively treat hypoglycemia and minimize time outside of the recommended blood glucose range, and also highlight the potential role of continuous glucose monitoring to assess glycemic status and responsiveness to therapies.”

Rezolute is currently enrolling patients into the second cohort of the Phase 2b RIZE study of RZ358, the Company’s monoclonal antibody for the treatment of HI, with topline data expected in Q1 of 2022.

About RZ358

RZ358 is an intravenously administered human monoclonal antibody that binds to a unique site (allosteric) on the insulin receptor throughout the body, such as in the liver, fat, and muscle. The antibody modifies insulin's binding and signaling to maintain glucose levels in a normal range which counteracts the effects of elevated insulin in the body. Rezolute believes that RZ358 is ideally suited as a potential therapy for conditions characterized by excessive insulin levels and is developing it to treat the hyperinsulinism and low blood sugar characteristic of diseases such as congenital hyperinsulinism (HI). As RZ358 acts downstream from the beta cells, it has the potential to be universally effective at treating HI caused by any of the underlying genetic defects.

Rezolute is currently evaluating RZ358 in the RIZE trial, a Phase 2b clinical study in patients with congenital hyperinsulinism. RZ358 received Orphan Drug Designation in the United States and European Union as well as Pediatric Rare Disease Designation in the US.

About Congenital Hyperinsulinism (HI)

Congenital HI is the most common cause of recurrent hypoglycemia in neonates and infants. It presents in neonates and infants as hypoglycemic episodes, with about 60% of infants with congenital HI experiencing a hypoglycemic episode within the first month of life. These episodes can result in significant brain injury and death if not recognized and managed appropriately. Recurrent hypoglycemic episodes and / or dangerously low blood sugars lead to progressive and irreversible damage over time, including serious and devastating brain and developmental problems. Although most patients with congenital HI can survive into adulthood, the damage from hypoglycemia can affect day-to-day functioning, with lasting symptoms such as seizures, developmental delay, and persistent feeding problems. To date, 14 genes have been found to be the cause of congenital HI. However, one-third or more of patients with congenital HI have an unknown genetic cause. The two most-commonly used long-term medications, diazoxide and octreotide, 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 a portion or the entire pancreas is required. In those with focal congenital HI where a small portion of the pancreas is affected, surgical removal of the specific affected area often results in a cure. 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 Rezolute, Inc.

Rezolute is developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company’s lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (HI), a rare pediatric endocrine disorder. The Company 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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