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): January 7, 2025

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 January 7, 2025, Rezolute, Inc. issued a press release to announce that the U.S. Food and Drug Administration granted Breakthrough Therapy Designation to ersodetug (previously RZ358) for the treatment of hypoglycemia due to congenital hyperinsulinism. A copy of this press release is attached hereto as Exhibit 99.1.

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 January 7, 2025

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: January 7, 2025

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

Exhibit 99.1

Rezolute Receives Breakthrough Therapy Designation from FDA for Ersodetug in the Treatment of Hypoglycemia Due to Congenital Hyperinsulinism

Breakthrough Therapy Designation granted based on key positive data from the Phase 2b (RIZE) study and current unmet medical need in congenital hyperinsulinism (HI)

Ersodetug continues to advance in clinical development as a potential treatment for hypoglycemia caused by all forms of hyperinsulinism; topline sunRIZE data expected second half of this year

REDWOOD CITY, Calif., January 07, 2025 — Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage biopharmaceutical company dedicated to developing transformative therapies for rare diseases with serious unmet needs, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to ersodetug (RZ358) for the treatment of hypoglycemia due to congenital HI.

Breakthrough Therapy Designation for ersodetug is designed to expedite the development and regulatory review of investigational treatments for serious or life-threatening conditions that, based on clinical evidence, have the potential to substantially improve clinical outcomes compared with available therapies. The Breakthrough Therapy Designation is based primarily on results from the Phase 2b (RIZE) study of ersodetug in participants with congenital HI, which safely demonstrated significant improvements in hypoglycemia of 75% or better, with no clinically significant hyperglycemia.

"2024 was a transformative year for Rezolute, marked by important clinical milestones and solid progress in advancing our mission to address hyperinsulinism in all forms," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "This Breakthrough Therapy Designation underscores the potential of ersodetug to make a meaningful difference for patients with hyperinsulinism. This year we are focused on finishing recruitment for sunRIZE and announcing topline results, as well as commencing our Phase 3 study for tumor HI."

Key highlights from 2024 include:

Clinical progress across two Phase 3 programs in two indications:

- Congenital HI
  - FDA lifted partial clinical holds on ersodetug thus enabling inclusion of U.S. clinical sites in an ongoing global Phase 3 sunRIZE study treating patients 3-months and older with congenital HI.
    - Topline results from sunRIZE expected in the second half of this year.
  - Rezolute received Innovation Passport Designation from the U.K. Innovative License and Access Pathway (ILAP) Steering Group for ersodetug for the treatment of hypoglycemia due to congenital HI.

- Tumor HI
  - Rezolute reported preclinical validation of the potential use of ersodetug for the treatment of hypoglycemia due to non-islet cell tumors (NICTs).
    - Combined with demonstrated potential in islet cell tumors (e.g. insulinoma), more than doubling the potential addressable patient population living with hypoglycemia resulting from tumor HI.

  - Rezolute received FDA clearance for an investigational new drug (IND) application for a Phase 3 registrational study of ersodetug for the treatment of hypoglycemia due to tumor HI.
    - Study start expected in the first half of 2025 and topline results expected in the second half of 2026.
  - FDA granted Orphan Drug Designation (ODD) to ersodetug for the treatment of hypoglycemia due to tumor HI.
  - More than 10 tumor HI patients to date have successfully been treated in the Expanded Access Program.

Strengthened financial position to advance pipeline and corporate strategy:

- The company raised $73 million in June, providing the financial resources needed to support its clinical programs and operational goals into Q2 2026.

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. More than half of children with congenital HI require long-term medical treatment for hypoglycemia that is not addressed by available therapies.

About Ersodetug

Ersodetug is a fully human monoclonal antibody that binds allosterically to the insulin receptor to counteract the effects of insulin receptor over-activation by insulin and related substances (such as IGF-2), thereby shifting over-signaling back into a more normalized range and improving hypoglycemia in the setting of hyperinsulinism (HI). Because ersodetug acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to any congenital or acquired form of HI.

About Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by hyperinsulinism (HI). The Company's antibody therapy, ersodetug, is designed to treat all forms of HI and has shown substantial benefit in clinical trials and real-world use for the treatment of congenital HI and tumor HI. 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," “potential,” 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 the FDA's grant of the Breakthrough Therapy Designation, the ersodetug Expanded Access Program, the ability of ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of ersodetug for the treatment of congenital hyperinsulinism, statements regarding clinical trial timelines for ersodetug, the timing of the Phase 3 sunRIZE study, and the FDA’s Orphan Drug Designation as it relates to ersodetug. 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 Rezolute’s Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are available on 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.

Contact:

Rezolute, Inc.
Christen Baglaneas
cbaglaneas@rezolutebio.com
508-272-6717