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 6, 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 March 6, 2024, Rezolute, Inc. issued a press release announcing the results from its preclinical pharmacology study on the use RZ358 as a potential treatment for hypoglycemia. 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 March 6, 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: March 11, 2024

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

Exhibit 99.1

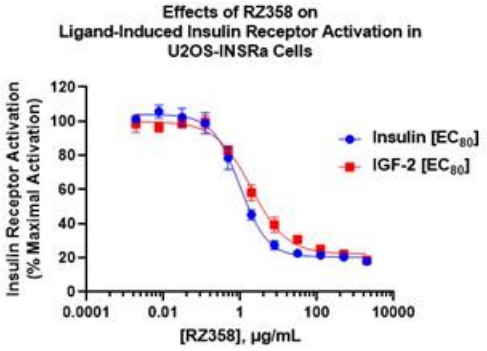
March 6, 2024

Rezolute Reports Validation of the Potential Use of RZ358 for Treatment of Non-Islet Cell Tumor Hypoglycemia (NICTH)

Potential to more than double the addressable patient population living with hypoglycemia resulting from insulin receptor over-activation (tumor hyperinsulinism)

REDWOOD CITY, Calif., March 06, 2024 (GLOBE NEWSWIRE) -- 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 results from a preclinical pharmacology study that validate the potential for its lead clinical compound, RZ358, to treat individuals with non-islet cell tumors (NICTs) that have uncontrolled hypoglycemia.

Tumor hyperinsulinism (HI) may be caused by a variety of different tumor types, resulting in islet cell tumor hypoglycemia (ICTH) and NICTH. The Company previously reported on the successful use of RZ358 under its Expanded Access Program (EAP) to treat patients with insulin-producing pancreatic islet cell tumors (ICTs), or insulinomas, causing severe and uncontrolled hypoglycemia. The therapeutic potential of RZ358 in this setting was anticipated given that ICTH is mediated by insulin and that RZ358 is known to work at the insulin receptor to decrease excess insulin binding and activity. However, it was unknown if RZ358 would have utility in NICTH where hyperinsulinism is mediated by hormones such as insulin-like growth factor-2 (IGF-2) or its variants, which likewise cause hypoglycemia by binding to and activating the insulin receptor. To test this, the Company recently completed in vitro pharmacology studies to evaluate the impact of clinically relevant concentrations of RZ358 on insulin receptor activation by IGF-2, compared to insulin. This was tested at the relative concentrations of each ligand that activate the insulin receptor and are physiologically relevant in tumor HI caused by ICTH and NICTH, respectively. These experiments successfully demonstrated the ability of RZ358 to similarly blunt both IGF-2 and insulin-mediated insulin-receptor signaling, at levels of these ligands that are disease- relevant in humans.



U2OS-INSRa Cell: a osteosacoma celline expressing insulin receptor isoform A

"These data demonstrate proof of the ligand-agnostic mechanism of action of RZ358 and therefore validate its broad utility in treating hypoglycemia resulting from any form of hyperinsulinism, including expanded tumor indications," said Dr. Brian Roberts, Chief Medical Officer of Rezolute. "Coupled with known outcomes from our clinical trials in congenital HI and the positive outcomes seen with ICTH in our expanded access program, we are excited by the potential for RZ358 to provide dramatic therapeutic benefit to cancer patients who often have limited treatment options for managing serious and uncontrolled hypoglycemia, which can accompany their cancer and disrupt treatment plans."

The Company recently reported on its successful interaction with the U.S. Food and Drug Administration (FDA) in January 2024 regarding the potential to initiate a single registrational study in patients with hypoglycemia due to tumor HI. The Company will continue to evaluate the feasibility of a development program in this indication, with the possibility of including both ICTH and NICTH patients. The inclusion of NICTH patients in a potential addressable market for RZ358 in tumor HI would more than double the population. The Company is also currently evaluating RZ358 in a Phase 3 clinical trial in congenital HI, which is a rare pediatric condition where, similar to ICTH, children overproduce insulin creating a dangerous hypoglycemic state.

About Tumor Hyperinsulinism (HI)

Tumor HI may be the result of two distinct types of tumors: islet cell tumors (ICTs) and non- islet cell tumors (NICTs), both of which lead to hypoglycemia due to excessive activation of the insulin receptor. Insulinomas are the most common type of functional ICT and cause hypoglycemia because of over production of insulin. NICTs can cause hypoglycemia by producing and secreting insulin-like paraneoplastic substances such as IGF-2 or related variants that bind to and activate the insulin receptor. This form of hypoglycemia can occur in more than 15 different tumor types, 60 percent of which are malignant, including hepatocellular carcinoma. The total addressable market for the combined indications causing tumor HI is estimated to be approximately 4,500 patients in the U.S. alone, including approximately 1,500 with ICTH and 3,000 with NICTH. The unique mechanism of action of RZ358 to attenuate excess insulin receptor activation mediated by insulin and related substances makes the therapy a potential universal treatment for hypoglycemia resulting from any form of hyperinsulinism.

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 in the liver, fat, and muscle. The antibody counteracts excess insulin receptor activation by insulin and other effector substances (such as IGF-2), thereby improving hypoglycemia. Because RZ358 acts downstream from the pancreas at the insulin receptor, 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). RZ358 received Orphan Drug Designation in the United States and European Union for the treatment of congenital HI, as well as Orphan Drug Designation and Pediatric Rare Disease Designation in the U.S. In the Phase 2 RIZE study, participants with congenital HI ages two and older nearly universally achieved

significant improvements 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 the Phase 3 study, RZ358 was generally safe and well-tolerated, and resulted in median improvements in hypoglycemia exceeding 80%. 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 Drug Designation status 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 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. 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 the Innovation Passport designation, 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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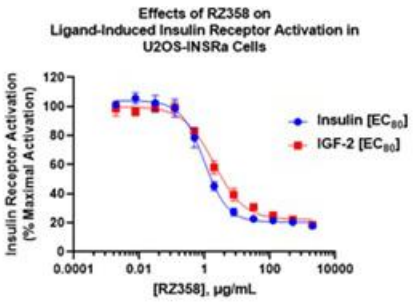
A photo accompanying this announcement is available at
https://www.globenewswire.com/NewsRoom/AttachmentNg/165f8dbc-1fce-47b8-ac3f- 0cf6fb4170cb

Source:
Rezolute, Inc.

Effects of RZ358 on Ligand-Induced Insulin Receptor Activation in U2OS-INSRa Cells



U2OS-INSRa Cell: a osteosacoma celline expressing insulin receptor isoform A

Effects of RZ358 on Ligand-Induced Insulin Receptor Activation in U2OS-INSRa Cells

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