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 19, 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 2.02 Results of Operations and Financial Condition.

On September 19, 2024, Rezolute, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended June 30, 2024. 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 September 19, 2024

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 19, 2024

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

Exhibit 99.1

Rezolute Reports Fourth Quarter and Full Year Fiscal 2024 Financial Results and Provides Business Update

FDA lifts partial clinical holds on ersodetug for the treatment of congenital HI; Phase 3 sunRIZE study to proceed in the U.S.

Phase 3 study for ersodetug for the treatment of tumor HI expected to commence in the first half of 2025

REDWOOD CITY, Calif., September 19, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stagebiopharmaceuticalcompany dedicated todevelopingtransformative therapies for rare diseases with serious unmet needs, today reported financial results and provided a business update for the fourth quarter and full fiscal year ended June 30, 2024.

"We are thrilled to close out the year with FDA alignment to advance ersodetug in two Phase 3 rare disease programs for the treatment of hypoglycemia resulting from congenital and acquiredforms of hyperinsulinism," said Nevan Elam, Chief Executive Officer and Founder of Rezolute. "The Phase 3 sunRIZE study remains on track for ex-U.S. participant enrollment and we expect U.S. enrollment to begin in the first part of 2025. We look forward to progressing both Phase 3 studies and remain excited at the prospect of ersodetug as a best-in-class treatment for hyperinsulinism based on the success we've seen to date."

Recent Pipeline Progress and Anticipated Milestones

Congenital HI

- U.S. Food and Drug Administration (FDA) removal of partial clinical holds on ersodetug, a potential treatment for hypoglycemia caused by congenital HI, and authorization of U.S. inclusion in the ongoing Phase 3 sunRIZE study.
    - Commencing study start-up activities in the U.S. with the goal of including U.S. participants in early 2025.
    - Ex-U.S. patient enrollment in sunRIZE is on track.
- Topline results from sunRIZE expected in the second half of 2025.

Tumor HI

- FDA clearance of Investigational New Drug (IND) application for Phase 3 registrational study for ersodetug for the treatment of hypoglycemia caused by tumor HI.
    - Start-up activities are ongoing for the study, which will be primarily conducted in the U.S., with patient enrollment anticipated to begin in the first half of 2025.
    - Topline results expected in mid-2026.
- Several insulinoma patients have been treated with ersodetug in the Expanded Access Program (EAP).

Diabetic Macular Edema (DME)

- Announced positive topline results in May of 2024 from the Phase 2 proof-of-concept study of RZ402 in patients with DME.
    - The study met primary endpoints, demonstrating good safety and tolerability, anda significant reduction in central subfield thickness (CST) in the Study Eye at all RZ402 dose levels compared to placebo (up to approximately 50 micron improvement).
    - We are actively engaged in conversations with potential partners to take RZ402 into further development.

Fourth Quarter and Full Year Fiscal 2024 Financial Results

Cash, cash equivalents and investments in marketable securities were $127.1 million as of June 30, 2024, compared with $118.4 million as of June 30, 2023.

Research and development (R&D) expenses were $19.1 million for the fourth quarter of fiscal 2024, compared with $10.9 million for the same period a year ago. Full fiscal year 2024 R&D expenses were $55.7 million, compared to $43.8 million in fiscal year 2023. The increase from fiscal year 2023 to fiscal year 2024 was primarily due to (i) increased expenditures in clinical trial activities, (ii) manufacturing costs for ersodetug, (iii) milestone payments due to license agreement partners, and (iv) higher employee-related expenses, which included employee compensation and stock-based compensation.

General and administrative (G&A) expenses were $4.0 million for the fourth quarter of fiscal 2024, compared with $3.3 million for the same period a year ago. Full fiscal year 2023 G&A expenses were $14.7 million, compared to $12.2 million in fiscal year 2023. The increase was primarily attributable to employee-related expenses due to increased headcount and professional fees.

Net loss was $23.0 million for the fourth quarter of fiscal 2024 compared with a net loss of $12.7 million for the same period a year ago. Full year fiscal 2024 net loss was $68.5 million compared to net loss of $51.8 million for the fiscal year 2023.

About Ersodetug

Ersodetug is a fully human monoclonal antibody that binds to a unique allosteric site on insulin receptors to counteract the effects of insulin receptor over-activation by insulin and related substances (such as IGF-2), thereby 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 form of HI.

About sunRIZE

The Phase 3 sunRIZE study is a multi-center, randomized, double-blind, placebo-controlled, parallel arm study designed to evaluate the efficacy and safety of ersodetug in

patients with congenital HI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study is enrolling up to 56 participants in more than a dozen countries around the world.

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," 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 fourth quarter and fiscal year financial results of Rezolute, the full year financial results of Rezolute, theersodetug Expanded Access Program,ersodetug as a sunRIZE Phase 3 study, 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 RZ402 study, the ability of RZ402 to become an effective treatment for diabetic macular edema, the effectiveness or future effectiveness of RZ402 to become an effective treatment for diabetic macular edema, and statements regarding clinical trial timelines for RZ402. 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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Rezolute, Inc.
Condensed Consolidated Financial Statements Data
(in thousands, except per share data)

	Three Months Ended June 30,		Year Ended June 30,	
	2024	**2023**	**2024**	**2023**
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 19,089	$ 10,933	$ 55,743	$ 43,813
General and administrative	4,013	3,305	14,680	12,177
Total operating expenses	23,102	14,238	70,423	55,990
Loss from operations	(23,102)	(14,238)	(70,423)	(55,990)
Non-operating (expenses) income, net	126	1,510	1,964	4,203
Net loss	$ (22,976)	$ (12,728)	$ (68,459)	$ (51,787)
Basic and diluted net loss per common share	$ (0.44)	$ (0.25)	$ (1.33)	$ (1.01)
Shares used to compute basic and diluted net loss per common share	52,235	51,410	51,465	51,188

	June 30, 2024	June 30, 2023
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 70,396	$ 16,036
Investments in marketable debt securities	56,741	102,330
Working capital	119,047	99,710
Total assets	132,737	123,721
Accumulated deficit	(329,444)	(260,985)
Total stockholders' equity	121,003	116,172