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): May 13, 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 2.02 Results of Operations and Financial Condition.

On May 13, 2025, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 31, 2025. 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 May 13, 2025
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: May 13, 2025

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

Exhibit 99.1

Rezolute Reports Third Quarter Fiscal 2025 Financial Results and Provides Business Update

sunRIZE enrollment on track including U.S. sites and expected to be completed in May 2025; topline data anticipated in December 2025

U.S. Food and Drug Administration (FDA) grants Breakthrough Therapy Designation to ersodetug for hypoglycemia due to tumor hyperinsulinism

REDWOOD CITY, Calif., May 13, 2025 -- Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage rare disease company focused on treating hypoglycemia caused by hyperinsulinism (HI), today reported financial results and provided a business update for the three months ended March 31, 2025.

"The Phase 3 sunRIZE study in congenital HI is on track to complete enrollment this month and we are poised to start our registrational upLIFT study for tumor HI mid-year," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "Each of our programs received Breakthrough Therapy Designation from FDA this year. We look forward to continued discussions with the agency with a focus on treating hypoglycemia caused by all forms of hyperinsulinism with the goal of advancing our novel therapy towards approval and commercialization."

Recent Pipeline Progress and Anticipated Milestones

Congenital HI

- sunRIZE, a Phase 3, multicenter, double-blind, randomized, controlled safety and efficacy registrational study, is ongoing and enrollment is expected to conclude in May 2025.
    - U.S. sites are activated and enrolling patients.
    - Topline results expected in December 2025.
- Upon completion of an interim analysis in April 2025, an independent Data Monitoring Committee recommended continuation of the sunRIZE study as planned without an increase to the study sample size.
    - The analysis was intended to evaluate the study for futility or otherwise to inform a potential sample size increase, for purposes of optimizing the study power and statistical confidence in the final analysis outcomes.
    - The Company remains blinded to the results.

Tumor HI

- In May 2025, FDA granted Breakthrough Therapy Designation (BTD) to ersodetug for the treatment of hypoglycemia due to tumor HI.
    - BTD was granted based on clinical trial data across the overall HI program and a recognition of the mechanistic applicability to tumor HI, further validated by real-world experience in tumor HI patients who have been successfully treated with ersodetug throughout the U.S. in the Company's Expanded Access Program.

- A registrational study for ersodetug in patients with tumor HI, the "upLIFT" study, is anticipated to begin in the middle of 2025 with topline data expected in the second half of 2026.
    - Utilizing BTD, the Company plans to engage further with FDA to discuss the registrational trial, including the necessary data package to support a BLA filing and potential approval for the tumor HI indication.

Corporate Updates

- In March 2025, the Company announced the appointment of rare disease commercial leader, Erik Harris, to its Board of Directors.
    - Mr. Harris is an experienced board member and commercial executive with a proven track record in the industry, currently serving as Chief Commercial Officer at Ultragenyx.
    - His insights will be invaluable as the Company advances through clinical development and prepares for potential commercialization.
- In April 2025, the Company announced the closing of an underwritten offering raising approximately $97 million.
    - Cash runway extended to middle of 2027.
    - The net proceeds will be used for research and development, general corporate expenses and working capital needs.

Fiscal Third Quarter Financial Results

Cash, cash equivalents and investments in marketable securities were $88.4 million as of March 31, 2025, compared to $127.1 million as of June 30, 2024.

Research and development expenses were $15.3 million for the third quarter of fiscal 2025, compared with $12.4 million for the same period a year ago, with the increase primarily attributable to increased expenditures in clinical trial activities, manufacturing costs and higher personnel-related expenses, which include employee compensation.

General and administrative expenses were $4.7 million for the third quarter of fiscal 2025, compared with $3.8 million for the same period a year ago, with the increase primarily attributable to professional fees and employee-related expenses as a result of increased headcount.

Net loss was $18.9 million for the third quarter of fiscal 2025 compared with a net loss of $17.1 million for the same period a year ago.

About Ersodetug

Ersodetug is a fully human monoclonal antibody that binds allosterically to the insulin receptor to decrease receptor over-activation by insulin and related substances (such as IGF-2) in the setting of hyperinsulinism (HI), thereby improving hypoglycemia. 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 treating 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 third quarter financial results of Rezolute, the efficacy of ersodetug in the congenital or tumor patient population, the timeline for the completion of enrollment or achieving results in either of our Phase 3 programs and the potential approval and commercialization of 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 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 March 31,		Nine Months Ended March 31,	
	2025	**2024**	**2025**	**2024**
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 15,283	$ 12,401	$ 40,664	$ 36,654
General and administrative	4,740	3,812	13,380	10,667
Total operating expenses	20,023	16,213	54,044	47,321
Loss from operations	(20,023)	(16,213)	(54,044)	(47,321)
Non-operating income (expense), net	1,109	(837)	4,022	1,838
Net loss	$ (18,914)	$ (17,050)	$ (50,022)	$ (45,483)
Basic and diluted net loss per common share	$ (0.27)	$ (0.34)	$ (0.72)	$ (0.89)
Shares used to compute basic and diluted net loss per common share	70,031	50,811	69,902	51,212

	March 31, 2025	**June 30, 2024**
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 14,596	$ 70,396
Investments in marketable debt securities	73,810	56,741
Working capital	78,208	119,047
Total assets	94,739	132,737

Accumulated deficit	(379,466)	(329,444)
Total stockholders' equity	82,569	121,003