
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): February 12, 2026

REZOLUTE, INC.
(Exact Name of Registrant as Specified in Charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-39683
(Commission
File Number)

27-3440894
(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 February 12, 2026, Rezolute, Inc. issued a press release announcing its financial results for the second quarter ended December 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.*

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated February 12, 2026</u>
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: February 12, 2026

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



Rezolute Reports Second Quarter Fiscal 2026 Financial Results and Provides Business Update

REDWOOD CITY, Calif., February 12, 2026 – Rezolute, Inc. (Nasdaq: RZLT) (“Rezolute” or the “Company”), a late-stage rare disease company focused on treating hypoglycemia caused by all forms of hyperinsulinism (HI), today reported financial results and provided a business update for the three months ended December 31, 2025.

Congenital Hyperinsulinism (HI)

- In December 2025, Rezolute reported topline results from sunRIZE, a Phase 3, multicenter, double-blind, randomized, placebo-controlled safety and efficacy study of ertsodetug for the treatment of congenital HI. The study did not meet its primary or key secondary endpoints.
 - The study demonstrated reductions from baseline in hypoglycemia events by self-monitored blood glucose at both ertsodetug dose levels, but reductions were not statistically significant compared to placebo, due to a pronounced study effect.
 - A reduction in hypoglycemia time by continuous glucose monitoring (CGM) was also demonstrated with both dose levels of ertsodetug, which was statistically significant compared to placebo at the Week 16 timepoint, but did not meet significance at the Week 24 end of pivotal timepoint.
 - In sunRIZE, pharmacologic activity was observed, with target therapeutic drug concentrations achieved in both treatment groups, along with highly sensitive biomarker responses of decreased insulin cell signaling in the active treatment groups, indicating drug activity.
 - Notably, all 59 participants who completed the study continued into the ongoing open-label extension portion, including the roll-over of placebo participants onto ertsodetug, and the vast majority remain on therapy. Some of the children have been able to stop taking their standard congenital HI therapies and are now receiving ertsodetug as monotherapy.
 - Subsequent to the announcement of the topline results of the primary and key secondary endpoints, the Company is undertaking extensive analysis of the results and other endpoints, in preparation for its upcoming FDA meeting.
 - The Company will be meeting with FDA prior to the end of the first quarter under Breakthrough Therapy Designation to determine next steps for the program.

Tumor HI

- upLIFT, a Phase 3, single-arm, open label study in up to 16 hospitalized participants for the treatment of tumor HI, is ongoing.
 - § Enrollment is underway and topline results are expected in the second half of 2026.
- In January 2026, the Company shared aggregate data from the initial 9 tumor HI patients treated under the historical Expanded Access Program (EAP).
 - § The data show that 75% of the patients receiving IV dextrose/total parenteral nutrition (TPN) in the EAP achieved a complete discontinuation of IV dextrose/TPN, providing additional evidence of the activity and potential efficacy of ertsodetug across various forms of HI.
 - § This cohort was the basis for FDA to grant Breakthrough Designation and agree to a single-arm, open-label registrational study design.

- § The glucose infusion rate (GIR) assessment in the EAP is the primary endpoint in upLIFT, which measures the number of participants (out of approximately 16) who achieve at least a 50% reduction in GIR.
- § The full EAP data table, filed on Form 8-K with the U.S. Securities and Exchange Commission, can be found [here](#).

Corporate Updates

- In November 2025, the Company hosted a virtual Investor Event during which Rezolute Chief Commercial Officer, Sunil Karnawat, discussed the anticipated commercial opportunities for ersodetug as a potential treatment for congenital and tumor HI. The event also featured presentations from two leading physician experts who provided perspectives on disease background and the significant unmet clinical need in HI.

- § A replay of the virtual event is available on the Investor Relations section of the Company's website [here](#).

Second Quarter Fiscal 2026 Financial Results

Cash, cash equivalents and investments in marketable securities were \$132.9 million as of December 31, 2025, compared with \$167.9 million as of June 30, 2025.

Research and development (R&D) expenses were \$14.3 million for the second quarter of fiscal 2026, compared with \$12.6 million for the same period a year ago. The increase from fiscal year 2025 to fiscal year 2026 was primarily due to (i) increased expenditures in clinical trial activities and (ii) higher employee-related expenses, which included one-time severance benefits related to the December 2025 reduction in force, partially offset by a decrease in manufacturing costs for ersodetug.

General and administrative (G&A) expenses were \$9.9 million for the second quarter of fiscal 2026, compared with \$4.5 million for the same period a year ago. The increase was primarily attributable to increased professional fees and employee-related expenses, which included one-time severance benefits related to the December 2025 reduction in force.

Net loss was \$22.8 million for the second quarter of fiscal 2026 compared with a net loss of \$15.7 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 been studied in clinical trials and used in real-world cases for the treatment of both congenital 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, the potential efficacy of ersodetug in treating hypoglycemia associated with either congenital or tumor HI, the possibility of FDA agreeing to a streamlined path for advancing the congenital HI program notwithstanding the lack of statistical significance in the sunRIZE study, or the timing of the release of topline results for upLIFT. 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 at the U.S. Securities and Exchange Commission'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 December 31,		Six Months Ended December 31,	
	2025	2024	2025	2024
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 14,348	\$ 12,627	\$ 27,497	\$ 25,381
General and administrative	9,873	4,453	16,541	8,640
Total operating expenses	24,221	17,080	44,038	34,021
Loss from operations	(24,221)	(17,080)	(44,038)	(34,021)
Non-operating income, net	1,447	1,350	3,114	2,913
Net loss	\$ (22,774)	\$ (15,730)	\$ (40,924)	\$ (31,108)
Basic and diluted net loss per common share	\$ (0.22)	\$ (0.22)	\$ (0.40)	\$ (0.45)
Shares used to compute basic and diluted net loss per common share	103,687	69,940	103,555	69,838
	December 31, 2025	June 30, 2025		
Condensed Consolidated Balance Sheets Data:				
Cash and cash equivalents	\$ 11,944	\$ 94,107		
Investments in marketable debt securities	120,994	73,751		
Working capital	125,577	159,233		
Total assets	138,629	175,490		
Accumulated deficit	(444,780)	(403,856)		
Total stockholders' equity	127,998	162,127		