

**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 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 May 12, 2026, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 31, 2026. 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>
99.1	Press Release, dated May 12, 2026
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 12, 2026

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



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

REDWOOD CITY, Calif., May 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 March 31, 2026.

Congenital Hyperinsulinism (HI)

- In May 2026, expanded analyses from the Phase 3 sunRIZE study of ersodetug in patients with congenital HI were presented via oral presentation at the Pediatric Endocrine Society (PES) 2026 Annual Meeting by Diva D. De León-Crutchlow, M.D., M.S.C.E., Chief of the Division of Endocrinology and Diabetes, Director of the Congenital Hyperinsulinism Center at Children’s Hospital of Philadelphia, and Principal Investigator of the sunRIZE study.
 - In addition to the previously reported topline results, the presentation included results from additional continuous glucose monitoring (CGM)-based outcomes, which demonstrated significant and consistent improvements in glycemic control in ersodetug treatment arms compared to placebo, across multiple pre-specified and post-hoc endpoints.
 - Average daily percent time in hypoglycemia by CGM: clinically relevant and nominally statistically significant reductions of >50% (Full Analysis Set [FAS]) and ~60-80% (Per Protocol Set [PPS]), compared to placebo across multiple timepoints
 - Average weekly hypoglycemia events by CGM: clinically relevant and nominally statistically significant reductions of ~50-65% (FAS) and ~50-80% (PPS), compared to placebo across multiple timepoints
 - Average daily AUC 70 to 180 mg/dL (Exposure to Normoglycemia) by CGM: clinically relevant and nominally statistically significant increases of ~25-50% (FAS and PPS), compared to placebo across multiple timepoints
 - Average blood glucose (mg/dL) by CGM: clinically relevant and nominally statistically significant increases of ~10-15% (~10-15 mg/dL) in both the FAS and PPS, compared to placebo across multiple timepoints
 - Participation, retention, and treatment duration in the open-label extension (OLE) following the completions of the study is high and has resulted in continued glycemic benefit, concurrent with the reduction and/or discontinuation of background standard of care therapies.
 - In March 2026, Rezolute announced outcomes from an in-person Type B meeting with the U.S. Food and Drug Administration (FDA) held on March 17, 2026, related to the sunRIZE study.
 - FDA acknowledged the challenges posed by the potential impact of varied behavioral factors on clinical trials in this heterogeneous patient population, including the associated limitations of self-monitored blood glucose (SMBG) based metrics in measuring hypoglycemia in congenital HI.
 - FDA encouraged Rezolute to submit comprehensive analysis datasets and summary outcomes for the agency’s independent evaluation.
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Tumor HI

- The Company expects to have an update on the program in the second half of 2026.
 - 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 in progress 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 full EAP data table, filed on Form 8-K with the U.S. Securities and Exchange Commission, can be found [here](#).

Third Quarter Fiscal 2026 Financial Results

Cash, cash equivalents and investments in marketable securities were \$120.3 million as of March 31, 2026, compared with \$167.9 million as of June 30, 2025.

Research and development (R&D) expenses were \$11.4 million for the third quarter of fiscal 2026, compared with \$15.3 million for the same period a year ago. The decrease from fiscal year 2025 to fiscal year 2026 was primarily due to (i) decreased manufacturing costs for ersodetug and (ii) decreased clinical trial activities. R&D expenses include \$1.9 million of share-based compensation expense for the third quarter of fiscal 2026, compared with \$0.9 million for the same period a year ago.

General and administrative (G&A) expenses were \$6.0 million for the third quarter of fiscal 2026, compared with \$4.7 million for the same period a year ago. The increase was primarily attributable to increased employee-related stock-based compensation expense, partially offset by a decrease in professional fees. G&A expenses include \$2.5 million of share-based compensation expense for the third quarter of fiscal 2026, compared with \$1.0 million for the same period a year ago.

Net loss was \$16.2 million for the third quarter of fiscal 2026 compared with a net loss of \$18.9 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 predictive nature of the CGM data as it relates to the potential efficacy of ersodetug in treating hypoglycemia, the ability of the Company to provide study reports and analysis datasets for the FDA's independent evaluation, the persuasiveness of the study reports and analysis datasets and the possibility of FDA agreeing to advance the congenital HI program based on those study reports and analysis datasets notwithstanding the lack of statistical significance in the sunRIZE study. 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 March 31,		Nine Months Ended March 31,	
	2026	2025	2026	2025
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 11,412	\$ 15,283	\$ 38,909	\$ 40,664
General and administrative	5,954	4,740	22,495	13,380
Total operating expenses	17,366	20,023	61,404	54,044
Loss from operations	(17,366)	(20,023)	(61,404)	(54,044)
Non-operating income, net	1,195	1,109	4,309	4,022
Net loss	\$ (16,171)	\$ (18,914)	\$ (57,095)	\$ (50,022)
Basic and diluted net loss per common share	\$ (0.16)	\$ (0.27)	\$ (0.55)	\$ (0.72)
Shares used to compute basic and diluted net loss per common share	104,040	70,031	103,714	69,902

	March 31, 2026	June 30, 2025
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	\$ 11,236	\$ 94,107
Investments in marketable debt securities	109,032	73,751
Working capital	114,345	159,233
Total assets	125,459	175,490
Accumulated deficit	(460,951)	(403,856)
Total stockholders' equity	116,834	162,127