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 24, 2026

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 24, 2026, Rezolute, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended June 30, 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*.

Exhibit No.	Description
99.1	Press Release, dated September 24, 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: September 24, 2026

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

Exhibit 99.1

Rezolute Reports Fourth Quarter and Full Year Fiscal 2026 Financial Results and Provides Business Update

REDWOOD CITY, Calif., September 24, 2026 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage ultra-rare rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI), today reported financial results and provided a business update for the fourth quarter and full fiscal year ended June 30, 2026.

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 in progress and topline results are expected before the end of 2026.
- In June 2026, the Company shared positive interim data from the upLIFT study, announcing that of the 8 participants enrolled, 6 had already met the responder criterion for the study's primary endpoint within the 8-week pivotal treatment phase. Each of these 6 participants also achieved a complete discontinuation of intravenous glucose requirements with the administration of ersodetug. *Since the time of this announcement, the seventh participant has also met the responder criterion for the study's primary endpoint.*
    - One of the 8 enrolled participants withdrew study consent and discontinued ersodetug and all other non-palliative therapies prior to completion of the pivotal treatment phase. This patient had Stage 4 metastatic colon cancer and a poor Eastern Cooperative Oncology Group performance status (ECOG 4). The participant elected to be discharged from the hospital to receive hospice care at home, where they died one week later due to cancer progression. The reduction and eventual discontinuation of intravenous glucose were undertaken in the setting of hospice transition, so the participant is being counted as a non-responder for purposes of assessing the primary endpoint.
- In June 2026 at the Annual Meeting of the Endocrine Society (ENDO), Rezolute delivered a poster presentation highlighting favorable outcomes from a case series report of 9 patients with refractory hypoglycemia due to malignant insulinoma and non-islet cell tumors (tumor HI), demonstrating that 75% of the patients receiving IV dextrose/total parenteral nutrition (TPN) in the EAP achieved a complete discontinuation of IV dextrose/TPN.
    - The outcomes of this case series were also recently published in manuscript form in The Journal of Clinical Endocrinology & Metabolism (JCEM), titled *Ersodetug for refractory hypoglycemia due to malignant insulin-secreting tumors*.

Congenital HI

- In September 2026, the Company provided an update that data from the Phase 3 sunRIZE study in congenital HI, which did not meet its primary endpoint, remains under review with the U.S. Food and Drug Administration (FDA or Agency).
    - In June 2026, the Company provided additional study data for the Agency's independent review, including source and analysis datasets and summary results from a substantial number of pre-specified, post-hoc, and sensitivity analyses with a focus on continuous glucose monitoring (CGM) based glucose outcomes from the pivotal portion of the study.
    - The open-label extension (OLE) phase of the sunRIZE study is ongoing, with a high participation rate and several indicators of improved glycemic control, including a notable reduction in the use of background standard of care therapies.

- Rezolute will continue to await feedback and reserves the ability to request a formal meeting under a regulatory timeline, as needed.

- In June 2026 at ENDO, Rezolute delivered three data presentations focused on congenital HI.
  - In an oral presentation, Huseyin Demirbilek, M.D., Professor, Department of Pediatric Endocrinology, Hacettepe University Faculty of Medicine, Ankara, Turkey, and Principal Investigator of the Phase 3 sunRIZE study, reviewed previously reported results from the study.
  - Two poster presentations highlighted results from systematic analyses of natural history and adverse neurologic and health-economic outcomes resulting from congenital HI, using a meta-analysis of the literature as well as a claims-based approach to quantifying congenital HI complications, respectively.

Fourth Quarter and Full Year Fiscal 2026 Financial Results

Cash, cash equivalents and investments in marketable securities were $107.8 million as of June 30, 2026, compared with $167.9 million as of June 30, 2025.

Research and development (R&D) expenses were $14.9 million for the fourth quarter of fiscal 2026, compared with $20.9 million for the same period a year ago. Full fiscal year 2026 R&D expenses were $53.8 million, compared to $61.5 million in fiscal year 2025. The decrease from fiscal year 2025 to fiscal year 2026 was primarily due to decreased manufacturing costs for ersodetug, partially offset by increased employee-related stock-based compensation expense. R&D expenses include $6.5 million of share-based compensation expense for the fiscal year 2026, compared with $3.5 million for fiscal year 2025.

General and administrative (G&A) expenses were $6.7 million for the fourth quarter of fiscal 2026, compared with $5.0 million for the same period a year ago. Full fiscal year 2026 G&A expenses were $29.2 million, compared to $18.4 million in fiscal year 2025. The increase was primarily attributable to increased employee-related stock-based compensation expense, and an increase in professional fees in preparation for future ersodetug commercial activities. G&A expenses include $8.0 million of share-based compensation expense for fiscal 2026, compared with $3.6 million for fiscal year 2025.

Net loss was $20.5 million for the fourth quarter of fiscal 2026 compared with a net loss of $24.4 million for the same period a year ago. Full year fiscal 2026 net loss was $77.6 million compared to net loss of $74.4 million for the fiscal year 2025.

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 pancreatic insulin or paraneoplastic IGF-2 secretion and from entero-incretin pathways, it has the potential to be universally effective at treating refractory hypoglycemia due to any form of hyperinsulinism (HI), including congenital HI, tumor HI (insulinoma, non-islet cell tumors) or bariatric/non-bariatric gastrointestinal surgery hypoglycemia. Ersodetug for the treatment of HI is investigational. Statements about safety and efficacy have not been approved by any health authority.

About Rezolute, Inc.

Rezolute is a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI). The Company's antibody therapy, ersodetug, has been studied in clinical trials and used in real-world cases for the treatment of refractory hypoglycemia due to a variety of causes of 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 as well as our ability to complete enrollment of the upLIFT study this year and announce topline results. Our ability to predict results or our plans or strategies is inherently uncertain. Notably, no assurance can be given that FDA will agree with the Company that there is evidence of clinically meaningful benefit observed in the sunRIZE study and accordingly the Agency could make the determination that the only path forward for the congenital HI indication is a new randomized control trial similar to sunRIZE. Should the Agency make such a determination, that would adversely impact the Company's ability to further pursue that indication as well as the commercial potential for ersodetug. 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 June 30,		Year Ended June 30,	
	2026	**2025**	**2026**	**2025**
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 14,889	$ 20,863	$ 53,798	$ 61,527
General and administrative	6,673	4,987	29,168	18,367
Total operating expenses	21,562	25,850	82,966	79,894
Loss from operations	(21,562)	(25,850)	(82,966)	(79,894)
Non-operating income, net	1,071	1,460	5,380	5,482
Net loss	$ (20,491)	$ (24,390)	$ (77,586)	$ (74,412)
Basic and diluted net loss per common share	$ (0.20)	$ (0.26)	$ (0.75)	$ (0.98)
Shares used to compute basic and diluted net loss per common share	104,488	94,340	103,907	75,999

	June 30, 2026	June 30, 2025
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 10,615	$ 94,107
Investments in marketable debt securities	97,186	73,751
Working capital	99,093	159,233
Total assets	112,849	175,490
Accumulated deficit	(481,442)	(403,856)
Total stockholders' equity	100,687	162,127