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): November 5, 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 November 5, 2026, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 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 November 5, 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: November 5, 2026

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

Exhibit 99.1

Rezolute Reports First Quarter Fiscal 2027 Financial Results and Provides Business Update

REDWOOD CITY, Calif., November 5, 2026 – Rezolute, Inc. (Nasdaq: RZLT) (Rezolute or the Company), a late-stage ultra-rare, metabolic 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 first quarter ended September 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 complete and topline results are expected by mid-December 2026.
- Earlier this year, the Company announced that 7 of the 8 participants enrolled in the first half of the study met the responder criterion for the study's primary endpoint.
  - Each of these participants also achieved complete discontinuation of intravenous glucose with the administration of ersodetug.
  - Ersodetug has been well-tolerated in the study thus far, with no drug-related safety findings reported.
  - The eighth participant in the first half of the study discontinued study drug shortly after enrollment in favor of pursuing hospice care at home, where they died one week later due to cancer progression. The Company considers this participant as a non-responder, for purposes of the primary endpoint.

Congenital HI

- In October 2026, the Company provided an update that the U.S. Food and Drug Administration (FDA or the Agency) has reviewed additional study data provided by the Company at the Agency's request.
- The Agency recommended the Company file for review under a Biologics License Agreement (BLA) for congenital HI after holding a pre-BLA meeting.
  - As previously reported, sunRIZE, a Phase 3, multicenter, double-blind, randomized, placebo-controlled safety and efficacy study of ersodetug for the treatment of congenital HI, demonstrated glycemic improvements, but did not meet the primary endpoint because the reductions in hypoglycemia events by finger-stick self-monitored blood glucose (SMBG) were not statistically significant compared to placebo. However, consistent and clinically relevant improvements in hypoglycemia were observed across multiple CGM-based hypoglycemia endpoints in both treatment arms.
  - 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.

Business Update

- On October 29, 2026, the Company participated in a virtual Q&A as part of Guggenheim's Healthcare Spotlight Series. The discussion focused on commercial outlook and launch strategy for ersodetug. Key highlights include:

- Potential $5 billion combined market opportunity.
- Plan to submit a BLA for ersodetug for one or potentially both indications in 2027.

First Quarter Fiscal 2027 Financial Results

Cash, cash equivalents and investments in marketable securities were $90.0 million as of September 30, 2026, compared with $107.8 million as of June 30, 2026.

Research and development (R&D) expenses were $12.8 million for the first quarter of fiscal 2027, compared with $13.1 million for the same period a year ago. The decrease was primarily due to decreased manufacturing costs for ersodetug and patient affairs costs, partially offset by increased employee-related stock-based compensation expense. R&D expenses include $1.5 million of share-based compensation expense for the first quarter of fiscal 2027, compared with $1.2 million for the same period a year ago.

General and administrative (G&A) expenses were $6.6 million for the first quarter of fiscal 2027, compared with $6.7 million for the same period a year ago. The decrease was primarily attributable to a decrease in professional fees, partially offset by increased employee-related stock-based compensation expense. G&A expenses include $1.8 million of share-based compensation expense for the first quarter of fiscal 2027, compared with $1.4 million for the same period a year ago.

Net loss was $18.5 million for the first quarter of fiscal 2027 compared with a net loss of $18.2 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 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, metabolic 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, statements regarding the potential safety, efficacy and therapeutic and commercial potential of ersodetug for the treatment of hypoglycemia caused by hyperinsulinism; the timing and results of the Phase 3 upLIFT study of ersodetug in tumor HI, including our expectation to announce topline results by mid-December 2026; the predictive nature of the CGM data and other findings from the sunRIZE study and its ongoing open-label extension as they relate to the potential efficacy of ersodetug in treating hypoglycemia; the persuasiveness of the additional study data reviewed by FDA and the possibility of FDA agreeing to advance the congenital HI program notwithstanding the lack of statistical significance for the primary endpoint in the sunRIZE study; the Company's plans and expectations regarding a pre-BLA meeting and the potential submission of a Biologics License Application (BLA) for ersodetug for one or both of tumor HI and congenital HI in 2027; the potential safety, efficacy and therapeutic potential of ersodetug for treating refractory hypoglycemia caused by any form of HI; and the commercial outlook and launch strategy for ersodetug, including the potential $5 billion combined market opportunity. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. With respect to congenital hyperinsulinism, although FDA has recommended that the Company file a BLA for review for congenital HI after holding a pre-BLA meeting, there can be no assurance that FDA will agree that the totality of evidence from the sunRIZE program demonstrates a clinically meaningful benefit or is sufficient to support approval of ersodetug for congenital HI. 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.

Rezolute Contacts:

Christen Baglaneas
Rezolute, Inc.
1411 Broadway, 16th Floor
New York, NY 10018
cbaglaneas@rezolutebio.com
508-272-6717

Carrie McKim
Rezolute, Inc.
1411 Broadway, 16th Floor
New York, NY 10018
cmckim@rezolutebio.com
336-608-9706

Rezolute, Inc.
Condensed Consolidated Financial Statements Data
(in thousands, except per share data)

	Three Months Ended September 30,	
	2026	**2025**
Condensed Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	$ 12,807	$ 13,149
General and administrative	6,578	6,668
Total operating expenses	19,385	19,817
Loss from operations	(19,385)	(19,817)
Non-operating income, net	898	1,667
Net loss	$ (18,487)	$ (18,150)
Basic and diluted net loss per common share	$ (0.18)	$ (0.18)
Shares used to compute basic and diluted net loss per common share	104,778	103,423

	September 30, 2026	**June 30, 2026**
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 8,150	$ 10,615
Investments in marketable debt securities	81,849	97,186
Working capital	84,370	99,093
Total assets	96,010	112,849
Accumulated deficit	(499,929)	(481,442)
Total stockholders' equity	85,948	100,687