

**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 6, 2025**

**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 |
|--------------------------------------------------|-------------------|-------------------------------------------|
| <b>Common Stock, par value \$0.001 per share</b> | <b>RZLT</b>       | <b>Nasdaq Capital Market</b>              |

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 6, 2025, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 30, 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>                                          |
|----------------------|-------------------------------------------------------------|
| <a href="#">99.1</a> | <a href="#">Press Release, dated November 6, 2025</a>       |
| 104                  | Cover Page Interactive Data File (formatted as inline XBRL) |

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**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 6, 2025

By: /s/ Nevan Charles Elam

Nevan Charles Elam  
Chief Executive Officer

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## Rezolute Reports First Quarter Fiscal 2026 Financial Results and Provides Business Update

**REDWOOD CITY, Calif., November 6, 2025 – Rezolute, Inc. (Nasdaq: RZLT) (“Rezolute” or the “Company”),** a late-stage rare disease company focused on treating hypoglycemia caused by hyperinsulinism, today reported financial results and provided a business update for the three months ended September 30, 2025.

“We remain on track to report topline results from the Phase 3 sunRIZE trial in congenital hyperinsulinism in December,” said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. “In tumor hyperinsulinism, following FDA alignment on our streamlined Phase 3 trial and with enrollment now underway, we expect to both complete enrollment and report topline data in the second half of next year. As we advance toward potential commercialization of ersodetug for the treatment of hyperinsulinism, we look forward to highlighting our progress at our investor event next week.”

### Recent Pipeline Progress and Anticipated Milestones

#### Congenital Hyperinsulinism (HI)

- sunRIZE, a Phase 3, multicenter, double-blind, randomized, placebo-controlled safety and efficacy study of ersodetug for the treatment of congenital HI, is ongoing.
  - § Topline results are expected in December 2025.
  - § Company has alignment with FDA that the study meets registrational requirements necessary for a BLA filing and review.

#### Tumor HI

- In August 2025, the Company achieved alignment with FDA on a significantly streamlined clinical development path for its Phase 3 registrational program of ersodetug for the treatment of tumor HI.
  - § A truncated, single-arm, open-label, Phase 3 study (upLIFT) in up to 16 hospitalized participants is considered acceptable as the adequate and well-controlled study to support registration, removing the need to conduct a double-blind randomized placebo-controlled trial.
  - § Enrollment is underway and topline results are expected in the second half of 2026.

### Corporate Updates

- On November 10, 2025, Rezolute will host a virtual Investor Event via webcast from 12:00-1:30 pm ET.
  - During the event, Rezolute Chief Commercial Officer, Sunil Karnawat, will discuss the anticipated commercial opportunities for ersodetug as a potential treatment for congenital and tumor HI. In addition, Rezolute management will review the Company’s ongoing clinical development programs, including the Phase 3 sunRIZE and upLIFT trials.
  - The call will also feature remarks from two leading physician experts in hyperinsulinism: Mansa Krishnamurthy, M.D., Pediatric Endocrinologist, Cincinnati Children’s Hospital Medical Center and Assistant Professor, Department of Pediatrics, University of Cincinnati; and Azeez Farooki, M.D., Attending Physician and Clinical Member, Endocrinology Service, Memorial Sloan Kettering Cancer Center and Associate Clinical Professor, Weill Cornell Medical College.

## **First Quarter Fiscal 2026 Financial Results**

Cash, cash equivalents and investments in marketable securities were \$152.2 million as of September 30, 2025, compared with \$167.9 million as of June 30, 2025.

Research and development (R&D) expenses were \$13.1 million for the first quarter of fiscal 2026, compared with \$12.8 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 employee compensation and stock-based compensation, partially offset by a decrease in manufacturing costs for ersodetug.

General and administrative (G&A) expenses were \$6.7 million for the first quarter of fiscal 2026, compared with \$4.2 million for the same period a year ago. The increase was primarily attributable to professional fees and employee-related expenses due to increased headcount.

Net loss was \$18.2 million for the first quarter of fiscal 2026 compared with a net loss of \$15.4 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 meaningful benefit in clinical trials and real-world use for the treatment of both congenital and tumor HI. For more information, visit [www.rezolutebio.com](http://www.rezolutebio.com).

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## 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 timing of the release of topline results from the sunRIZE trial, the applicability of ersodetug across multiple forms of hyperinsulinism, the timing of the release of topline results from the upLIFT study, the ability of ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of ersodetug for the treatment of congenital hyperinsulinism, and statements regarding clinical trial timelines for 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](http://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:

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

|                                                                    | Three Months Ended<br>September 30, |                    |
|--------------------------------------------------------------------|-------------------------------------|--------------------|
|                                                                    | 2025                                | 2024               |
| <b>Condensed Consolidated Statements of Operations Data:</b>       |                                     |                    |
| Operating expenses:                                                |                                     |                    |
| Research and development                                           | \$ 13,149                           | \$ 12,754          |
| General and administrative                                         | 6,668                               | 4,187              |
| Total operating expenses                                           | 19,817                              | 16,941             |
| Loss from operations                                               | (19,817)                            | (16,941)           |
| Non-operating income (expenses), net                               | 1,667                               | 1,563              |
| Net loss                                                           | <u>\$ (18,150)</u>                  | <u>\$ (15,378)</u> |
|                                                                    |                                     |                    |
| Basic and diluted net loss per common share                        | <u>\$ (0.18)</u>                    | <u>\$ (0.22)</u>   |
|                                                                    |                                     |                    |
| Shares used to compute basic and diluted net loss per common share | <u>103,423</u>                      | <u>69,736</u>      |
|                                                                    |                                     |                    |
|                                                                    | September 30,                       | June 30,           |
|                                                                    | 2025                                | 2025               |
| <b>Condensed Consolidated Balance Sheets Data:</b>                 |                                     |                    |
| Cash and cash equivalents                                          | \$ 9,098                            | \$ 94,107          |
| Investments in marketable debt securities                          | 143,096                             | 73,751             |
| Working capital                                                    | 144,499                             | 159,233            |
| Total assets                                                       | 158,664                             | 175,490            |
| Accumulated deficit                                                | (422,006)                           | (403,856)          |
| Total stockholders' equity                                         | 147,168                             | 162,127            |