

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): October 14, 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 7.01 Regulation FD Disclosure.

On October 14, 2026, Rezolute, Inc. (the "Company") issued a press release to announce an update on patient enrollment in the Company's upLIFT study.

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.

The release contains forward looking statements. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of the Company, are generally identified by use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "prove," "potential," "seek," "strive," "try," or future or conditional verbs such as "predict," "could," "may," "likely," "should," "will," "would," or similar expressions. The Company's ability to predict results or the actual results of the Company's plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers of the poster are cautioned not to place undue reliance on these forward-looking statements. Except as required by applicable law or regulation, the Company 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 the Company's filings with the SEC, including the Risk Factors contained in the Company'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.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated October 14, 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: October 14, 2026

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

Rezolute Announces Completion of Enrollment in Phase 3 upLIFT Study of Ersodetug in Tumor Hyperinsulinism

Topline results expected mid-December 2026

REDWOOD CITY, Calif., October 14, 2026 – Rezolute, Inc. (Nasdaq: RZLT) (Rezolute or Company), a late-stage ultra-rare disease company focused on treating refractory hypoglycemia caused by any form of hyperinsulinism (HI), today announced that the open-label Phase 3 study of ersodetug in tumor HI (upLIFT) is now fully enrolled and topline data are expected mid-December 2026. The Company plans to continue its expanded access program for purposes of providing ersodetug on a compassionate use basis to individuals living with serious and refractory hypoglycemia due to tumor HI.

The upLIFT study is a single-arm, open-label, registrational study in 16 participants with insulinoma or non-islet cell tumors who have uncontrolled hypoglycemia caused by tumor HI. The study's primary endpoint is the percent of participants who require intravenous glucose for refractory hypoglycemia that achieve at least a 50 percent reduction from baseline in glucose infusion rate (GIR) within the 8-week pivotal treatment phase. For statistical significance, the lower bound of the 95% confidence interval (CI) for the percent responder rate must be $\geq 30\%$, equating to a response rate of at least 56% (95% CI of 30-80%) for 16 participants.

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. Furthermore, 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 elected to pursue hospice care at home shortly after enrollment, 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.

"Completing enrollment in the upLIFT study marks an important milestone as we advance a potentially transformative treatment option for patients living with tumor hyperinsulinism," said Dr. Brian Roberts, Chief Medical Officer at Rezolute. "Now that we have a path forward for congenital hyperinsulinism, we look forward to announcing topline data from upLIFT and to the extent the study outcomes are favorable, the potential to advance both indications in 2027. We are deeply grateful to the patients, families, investigators and advocacy groups whose dedication and partnership have enabled us to reach this point."

About upLIFT

The upLIFT Phase 3 registrational study is a single-arm, open-label, pivotal trial in approximately 16 participants with insulinoma or non-islet cell tumors who have uncontrolled hypoglycemia caused by tumor hyperinsulinism (HI). Eligible participants requiring continuous intravenous (IV) glucose will receive ersodetug 9 mg/kg per week for 8 weeks, as an add-on to standard of care. Following this 8-week pivotal treatment period, all participants may receive ersodetug in long-term extension. The primary endpoint is the proportion of participants able to achieve at least a 50 percent reduction from baseline in IV glucose requirements (glucose infusion rate; GIR). Additional endpoints include the number of participants achieving discontinuation of GIR and time to discontinuation, time to discharge from the hospital, extent of hypoglycemia events and hypoglycemia time in the outpatient setting by self-monitored blood glucose and continuous glucose monitor, respectively, and patient reported quality of life.

About Tumor Hyperinsulinism

Tumor hyperinsulinism (HI) is a rare disease that may be caused by two distinct types of tumors: islet cell tumors (ICTs) and non-islet cell tumors (NICTs), both of which lead to hypoglycemia because of over-activation of the insulin receptor. Insulinomas are the most common type of ICT and cause hypoglycemia by stimulating the overproduction of insulin. A variety of different NICTs, including hepatocellular carcinoma and soft tissue malignancies (e.g. sarcomas), can cause hypoglycemia by producing and secreting insulin-like paraneoplastic substances, such as variants of IGF-2, that bind to and activate the insulin receptor. With high morbidity and mortality rates within tumor HI, there remains a significant unmet need for new therapies directed at hypoglycemia treatment. Ersodetug has shown real-world benefit in patients with insulinoma and NICTs.

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 HI, including congenital HI, tumor HI (insulinoma, non-islet cell tumors) and 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 announce upLIFT topline results this year. Further, even if the upLIFT study results meet the specified endpoint and the study is a success, there can be no assurance that regulatory authorities will ever approve ersodetug for the treatment of tumor or congenital hyperinsulinism. Our ability to predict results or our plans or strategies is inherently uncertain. 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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