

**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 7, 2024

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 November 7, 2024, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 30, 2024. 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>
<u>99.1</u>	<u>Press Release, dated November 7, 2024</u>

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 7, 2024

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



Rezolute Reports First Quarter Fiscal 2025 Financial Results and Provides Business Update

Ersodetug, a novel, fully human monoclonal antibody for the treatment of hyperinsulinism (HI), advancing in two late-stage, registrational clinical trials in two indications

Phase 3 sunRIZE study on track; U.S. enrollment expected to commence in the first part of 2025

Phase 3 tumor HI study expected to commence in the first half of 2025

REDWOOD CITY, Calif., November 07, 2024 – Rezolute, Inc. (Nasdaq: RZLT) (“Rezolute” or the “Company”), a late-stage biopharmaceutical company dedicated to developing transformative therapies for rare diseases with serious unmet needs, today reported financial results and provided a business update for the three months ended September 30, 2024.

“Execution across our two Phase 3 programs in patients with congenital HI and tumor HI will be the focus going into 2025,” said Nevan Elam, Chief Executive Officer and Founder of Rezolute. “We are pleased with the progress we’ve made in sunRIZE enrollment and look forward to advancing our Phase 3 study in tumor HI patients based on the success demonstrated in our Expanded Access Program. As a rare disease company with two late-stage clinical trials, we recognize how critical 2025 will be in progressing our programs in order to provide a potentially meaningful therapy for patients where limited options currently exist.”

Recent Pipeline Progress and Anticipated Milestones

Congenital HI

- Ex-U.S. patient enrollment in sunRIZE, a global, pivotal Phase 3 clinical study for ersodetug in patients with congenital HI, is on track.
- Study start-up activities are underway for enrollment of U.S. participants in early 2025.
- Topline results from sunRIZE expected in the second half of 2025.

Tumor HI

- Start-up activities are progressing for the Phase 3 registrational study for ersodetug in patients with tumor HI.
- Patient enrollment anticipated to begin in the first half of 2025.
- Topline results expected in the second half of 2026.

Fiscal First Quarter Financial Results

Cash, cash equivalents and investments in marketable securities were \$117.8 million as of September 30, 2024, compared to \$127.1 million as of June 30, 2024.

Research and development expenses were \$12.8 million for the first quarter of fiscal 2025, compared with \$12.2 million for the same period a year ago, with the increase primarily attributable to increased expenditures in clinical trial activities, manufacturing costs and higher personnel-related expenses, which include employee compensation.

General and administrative expenses were \$4.2 million for the first quarter of fiscal 2025, compared with \$3.7 million for the same period a year ago, with the increase primarily attributable to professional fees and employee-related expenses as a result of increased headcount.

Net loss was \$15.4 million for the first quarter of fiscal 2025 compared with a net loss of \$14.5 million for the same period a year ago.

About Ersodetug

Ersodetug is a fully human monoclonal antibody that binds to a unique allosteric site on insulin receptors to counteract the effects of insulin receptor over-activation by insulin and related substances (such as IGF-2), thereby improving hypoglycemia in the setting of hyperinsulinism (HI). Because ersodetug acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to any form of HI.

About sunRIZE

The Phase 3 sunRIZE study is a multi-center, randomized, double-blind, placebo-controlled, parallel arm study designed to evaluate the efficacy and safety of ersodetug in patients with congenital HI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study is enrolling up to 56 participants in more than a dozen countries around the world.

About Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by hyperinsulinism (HI). The Company’s antibody therapy, ersodetug, is designed to treat all forms of HI and has shown substantial benefit in clinical trials and real-world use for the treatment of congenital HI 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 statements regarding the first quarter financial results of Rezolute, the ersodetug Expanded Access Program, ersodetug as a sunRIIZE Phase 3 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, statements regarding clinical trial timelines for ersodetug, the RZ402 study, the ability of RZ402 to become an effective treatment for diabetic macular edema, the effectiveness or future effectiveness of RZ402 to become an effective treatment for diabetic macular edema, and statements regarding clinical trial timelines for RZ402. 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. 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.

Contact:

Rezolute, Inc.

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

	Three Months Ended September 30,	
	2024	2023
Condensed Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	\$ 12,754	\$ 12,214
General and administrative	4,187	3,700
Total operating expenses	16,941	15,914
Loss from operations	(16,941)	(15,914)
Non-operating income (expense), net	1,563	1,390
Net loss	\$ (15,378)	\$ (14,524)
Basic and diluted net loss per common share	\$ (0.22)	\$ (0.28)
Shares used to compute basic and diluted net loss per common share	69,736	51,409
	September 30, 2024	September 30, 2023
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	\$ 10,472	\$ 8,057
Investments in marketable debt securities	107,353	98,817
Working capital	102,187	95,450
Total assets	123,414	112,999
Accumulated deficit	(344,822)	(275,509)
Total stockholders' equity	113,441	103,564