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): May 15, 2024

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 May 15, 2024, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 31, 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.

Exhibit No.	Description
99.1	Press Release, dated May 15, 2024
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: May 15, 2024

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

Exhibit 99.1

Rezolute Reports Third Quarter Fiscal 2024 Financial Results and Provides Business Update

Patient enrollment underway in sunRIZE global Phase 3 clinical study of RZ358 in patients with congenital hyperinsulinism (cHI); topline results expected in mid-2025

Completed in-vivo toxicology study in brown Norway rats; early results show no abnormalities at highest tested dose of RZ358

Continue to engage in productive interactions with FDA towards resolution of partial clinical holds and path forward for potential late-stage, registrational, clinical study in tumor hyperinsulinism (HI)

REDWOOD CITY, Calif., May 15, 2024 – Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today reported financial results and provided a business update for the three months ended March 31, 2024.

"In the past few months, we have been focused on global site activation and patient enrollment for sunRIZE, a pivotal Phase 3 clinical study of RZ358 in patients with congenital hyperinsulinism. We have also completed dosing of patients with diabetic macular edema for our Phase 2 multi-center clinical study of RZ402 and we expect to announce topline results from that study this month," said Nevan Elam, Chief Executive Officer and Founder of Rezolute. "Additionally, in the U.S. we continue to have productive interactions with FDA as we work towards achieving liberalization of the partial clinical holds on sunRIZE."

Recent Pipeline Progress and Anticipated Milestones

Congenital Hyperinsulinism (cHI)

- Patient enrollment underway in sunRIZE, a global, pivotal Phase 3 clinical study of RZ358 in patients with cHI in Europe and other geographies outside of the U.S.
  - Enrollment is expected to complete by the end of 2024.
  - Topline results expected in mid-2025.

- As part of the effort to resolve the partial clinical holds in the U.S., the Company conducted and recently completed an in-vivo toxicology study in brown Norway rats using Sprague Dawley (SD) rats as a positive control.
  - Early results show that at the highest tested dose of 40 mg/kg, there were no observed liver abnormalities in the brown Norway rat, which is approximately four times higher than the dose that results in microvascular liver abnormalities in SD rats. Additionally, at the 40 mg/kg dose in this study, SD rats had liver abnormalities consistent with previous in-vivo studies.
  - The Company believes that the Norway rat study adds to the body of evidence that the rat findings are specific to the SD rat and are not otherwise relevant, based on the absence of findings in other rat strains, other rodent species (CD-1 mice), primates, and humans in studies to date.

  - Final data tabulations and a report for this study will be completed in the coming weeks. The company plans to submit this study as well as additional in-vitro information to the FDA this summer as part of a complete response to the partial clinical holds.

Tumor Hyperinsulinism (HI)

- Alignment with FDA to conduct a potential late-stage, registrational, clinical study in both non-islet cell tumor hypoglycemia (NICTH) and insulinoma patients, which would be the second development program and rare disease indication for RZ358.
- To date, five metastatic insulinoma patients have been treated with RZ358 in the Expanded Access Program (EAP).
- Potential initiation of a development program for this indication is currently under evaluation by the Company. Updates will be provided later this year.

Diabetic Macular Edema (DME)

- Completed patient dosing for Phase 2 U.S., multi-center clinical study in 94 participants with DME who are naïve to or have received limited anti-VEGF injections.
  - Primary endpoints include (i) stabilization of disease and/or change in study eye macular central subfield thickness, as measured by Spectral Domain Ocular Coherence Tomography, (ii) change in study eye visual acuity as measured by the early treatment diabetic retinopathy scale, (iii) the repeat dose pharmacokinetics of RZ402 in patients with DME, and (iv) the safety and tolerability of RZ402.
  - Topline results expected in May 2024.

Fiscal Third Quarter Financial Results

Cash, cash equivalents and investments in marketable securities were $81.6 million as of March 31, 2024, compared with $118.4 million as of June 30, 2023.

Research and development expenses were $12.4 million for the third quarter of fiscal 2024, compared with $14.2 million for the same period a year ago, with the decrease primarily attributable to a reduction in milestone expense of $3.0 million due to Phase 2 dosing milestone triggered in RZ402, with no comparative expense incurred in the current year, offset partially by an increase of R&D personnel-related expenses due to increased headcount.

General and administrative expenses were $3.8 million for the third quarter of fiscal 2024, compared with $2.9 million for the same period a year ago, with the increase primarily attributable to personnel-related expenses due to increased headcount.

Net loss was $17.1 million for the third quarter of fiscal 2024 compared with a net loss of $15.7 million for the same period a year ago.

About Rezolute, Inc.

Rezolute strives to disrupt current treatment paradigms by developing transformative therapies for devastating rare and chronic metabolic diseases. Its novel therapies hold the potential to significantly improve outcomes and to reduce the treatment burden for patients, treating physicians and the healthcare system. Rezolute is steadfast in its mission to create a profound, positive and lasting impact on the lives of patients. Patient, clinician and advocate voices are integrated in the Company's drug development process. Rezolute places an emphasis on understanding the patient's lived experiences, enabling the Company to boldly address a range of severe conditions. 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 third quarter financial results of Rezolute, the RZ358 Expanded Access Program, the ability of RZ358 to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of RZ358 for the treatment of congenital hyperinsulinism, statements regarding clinical trial timelines for RZ358, 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.

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2024	2023	2024	2023
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	$ 12,401	$ 14,231	$ 36,654	$ 32,880
General and administrative	3,812	2,911	10,667	8,872
Total operating expenses	16,213	17,142	47,321	41,752
Loss from operations	(16,213)	(17,142)	(47,321)	(41,752)
Non-operating (expenses) income, net	(837)	1,470	1,838	2,693
Net loss	$ (17,050)	$ (15,672)	$ (45,483)	$ (39,059)
Basic and diluted net loss per common share	$ (0.34)	$ (0.30)	$ (0.89)	$ (0.76)
Shares used to compute basic and diluted net loss per common share	50,811	51,409	51,212	51,113

	March 31, 2024	June 30, 2023
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 5,930	$ 16,036
Investments in marketable debt securities	75,665	102,330
Working capital	75,253	99,710
Total assets	87,737	123,721
Accumulated deficit	(306,468)	(260,985)
Total stockholders' equity	70,861	116,172