

**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 13, 2023

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 13, 2023, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 30, 2023. 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 13, 2023
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 13, 2023

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



Rezolute Reports First Quarter Fiscal 2024 Results

Redwood City, Calif., November 13, 2023 -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced its financial results for the first quarter of fiscal 2024 ended September 30, 2023.

"We are on track to commence our Phase 3 study for RZ358 to treat congenital hyperinsulinism prior to year-end and are delighted to have recently obtained PRIME eligibility from the European Medicines Agency for this indication," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We also anticipate completing enrollment this quarter for our ongoing Phase 2 study of RZ402 for the treatment of diabetic macular edema and plan to provide an update on the study prior to year end."

Clinical Highlights

- RZ358, a monoclonal antibody for the treatment of hyperinsulinism
 - o Received EMA priority medicines (PRIME) designation for the treatment of congenital hyperinsulinism (cHI) from the European Medicines Agency
 - o Plan to initiate sunRIZE, a pivotal Phase 3 clinical study in patients with cHI, in Europe and other geographies outside the US in the fourth quarter 2023
 - o Continuing the administration of RZ358 in the US with FDA approval under a compassionate use program to treat patients with tumor associated hyperinsulinism, including for a patient with refractory hypoglycemia due to metastatic insulinoma who has remained on RZ358 for nearly a year
- RZ402, an oral plasma kallikrein inhibitor in Phase 2 to treat diabetic macular edema (DME)
 - o Multi-center, randomized, double-masked, placebo-controlled, parallel-arm study ongoing to evaluate the safety, efficacy, and pharmacokinetics of RZ402 administered as a monotherapy over a 12-week treatment period in participants with DME who are naïve to or have received limited anti-VEGF injections
 - o Study is in the latter stages of patient recruitment and an update on the study will be provided prior to year end

First Quarter Fiscal 2024 Financial Results

- Cash, cash equivalents and investments in marketable debt securities totaled \$106.9 million as of September 30, 2023, compared to \$118.4 million as of June 30, 2023



- Research and development expenses were \$12.2 million for the first quarter of fiscal 2024, compared to \$7.7 million for the same period in fiscal 2023, with the increase primarily attributable to increased expenditures in clinical trial activities, manufacturing costs and higher personnel-related expenses, which included employee compensation and stock-based compensation
- General and administrative expenses were \$3.7 million for the first quarter of fiscal 2024, compared to \$2.5 million for the same period in fiscal 2023, with the increase primarily attributable to higher personnel-related expenses, including employee compensation and stock-based compensation
- Net loss was \$14.5 million for the first quarter of fiscal 2024, compared to \$9.8 million for the same period in fiscal 2023

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 both significantly improve outcomes and reduce the treatment burden for patients, treating physicians, and the healthcare system. Rezolute is steadfast in its mission to create profound, positive, and lasting impacts on patients' lives. 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 and statements regarding PRIME designation and the designation's meaning on the ability of RZ358 to become an effective treatment to congenital HI, the effectiveness or future effectiveness of RZ358 for the treatment of congenital HI, and statements regarding clinical trial timelines for RZ358. 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.

Investors:

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

	Three Months Ended September 30,	
	2023	2022
Condensed Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	\$ 12,214	\$ 7,704
General and administrative	3,700	2,514
Total operating expenses	15,914	10,218
Loss from operations	(15,914)	(10,218)
Non-operating income (expense), net	1,390	387
Net loss	\$ (14,524)	\$ (9,831)
Basic and diluted net loss per common share	\$ (0.28)	\$ (0.19)
Shares used to compute basic and diluted net loss per common share	51,409	50,528
	September 30, 2023	June 30, 2023
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	\$ 8,057	\$ 16,036
Investments in marketable debt securities	98,817	102,330
Working capital	95,450	99,710
Total assets	112,999	123,721
Accumulated deficit	(275,509)	(260,985)
Total stockholders' equity	103,564	116,172