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 11, 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)

<u>650-206-4507</u> Registrant's Telephone Number, Including Area Code

<u>Not Applicable</u> (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))
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- ☐ 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. \Box

Item 2.02 Results of Operations and Financial Condition.

On May 11, 2023, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 31, 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 May 11, 2023

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 11, 2023

By: /s/Nevan Charles Elam Nevan Charles Elam

Nevan Charles Elam Chief Executive Officer

Rezolute Reports Third Quarter Fiscal 2023 Results and Highlights Company Progress

The Company is poised to commence Phase 3 for RZ358 in the third quarter of calendar year 2023

REDWOOD CITY, Calif., May 11, 2023 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to shift the treatment paradigms of devastating metabolic diseases, today announced its financial results for the third quarter of fiscal 2023 ended March 31, 2023.

"We are continuing to make progress across our pipeline, including preparation for a Phase 3 study for RZ358 as well as enrollment of patients in our Phase 2 Study for RZ402," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "The quarter was punctuated by a Rezolute-hosted virtual key opinion leader event that explored the therapeutic landscape of diabetic macular edema and the rationale for treating with an oral plasma kallikrein inhibitor such as RZ402.I am excited and encouraged by the support of key thought leaders in the ophthalmology space who, like all of us at Rezolute, wish to change the treatment paradigm of DME."

Third Quarter Fiscal 2023 Financial Results

- · Cash and cash equivalents totaled \$33.7 million and investments in marketable debt securities totaled \$95.5 million as of March 31, 2023.
- Research and development (R&D) expenses were \$14.2 million for the third quarter of fiscal 2023, compared to \$8.7 million for the same period in fiscal 2022. The increase was primarily due 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 (G&A) expenses were \$2.9 million for the third quarter of fiscal 2023, compared to \$2.1 million for the same period in fiscal 2022. The increase was primarily due to higher personnel-related expenses, including employee compensation and stock-based compensation.
- Net loss was \$15.7 million for the third guarter of fiscal 2023, compared to \$11.2 million for the same period in fiscal 2022.

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, the treating physician, and the healthcare system. Patient, clinician, and advocate voices are integrated in the Company's drug development process, enabling Rezolute to boldly address a range of severe conditions. Rezolute is steadfast in its mission to create profound, positive, and lasting impact on patients' lives. The Company's lead clinical asset, RZ358, is in late-stage development for the treatment of congenital hyperinsulinism, a rare pediatric endocrine disorder. Rezolute is also developing RZ402, an orally available plasma kallikrein inhibitor, for the treatment of diabetic macular edema. For more information, visit www.rezolutebio.com or follow us on Twitter.

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. 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 Rezolute's 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

Investor:

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

	March 31,				March 31,			
	2023		2022		2023		2022	
	(unaudited)			(unaudited)				
Ф	14.221	Ф	0.606	Ф	22.000	0	22.012	
\$	14,231	\$	8,686	\$	32,880	\$	23,912	
	2.911		2.068		8 872		6.632	

41,752

(41,752)

2,693

(39,059)

(0.76)

30,544

(30,544)

(1,093)

(31,637)

(2.30)

10,754

(10,754)

(11,208)

(454)

(0.65)

17,142

(17,142)

1,470

(0.30)

(15,672)

Shares used to compute basic and diluted net loss per common share	51,409	17,218	51,11	3 13,748	
		March 31, 2023 (unaudited)		June 30, 2022	
Condensed Consolidated Balance Sheets Data:		Ì			
Cash and cash equivalents		\$	33,743 \$	150,410	
Investments in marketable debt securities		9	95,529	-	
Working capital		1	01,139	149,642	
Total assets		1:	34,205	152,420	
Accumulated deficit		(24	48,257)	(209,198)	
Total stockholders' equity		1:	27,316	149,471	

Condensed Consolidated Statements of Operations Data:

Operating expenses:

Loss from operations

Net loss

Research and development General and administrative

Total operating expenses

Non-operating income (expense), net

Basic and diluted net loss per common share