

**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): September 14, 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 September 14, 2023, Rezolute, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended June 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated September 14, 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: September 14, 2023

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



Rezolute Reports Full Year Fiscal 2023 Results and Highlights Company Progress

Planning to initiate Phase 3 Study for RZ358 (“sunRIZE study”) in the fourth quarter of 2023

REDWOOD CITY, Calif., Sept. 14, 2023 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to disrupt treatment paradigms for devastating metabolic diseases, today announced its financial results for the fourth quarter and full fiscal year ended June 30, 2023.

“We are delighted that we are poised to initiate sunRIZE -- our Phase 3 study of RZ358, which we hope will bring us one step closer to making this therapy available to patients and their families suffering from congenital hyperinsulinism. We are also anticipating results from our Phase 2 study of RZ402 in the first quarter of 2024, where we hope to demonstrate the safety and proof-of-concept of our oral therapy for diabetic macular edema,” said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. “As we look ahead to these upcoming milestones, we remain committed to our mission of delivering transformative therapies to patients with devastating metabolic diseases.”

Corporate and Clinical Highlights

- RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism (HI)**
 - Following the successful Phase 2b RIZE study of RZ358 in congenital HI, which demonstrated that RZ358 safely and substantially improved hypoglycemia, the Company plans to initiate sunRIZE, a pivotal Phase 3 clinical study of RZ358, in Europe and other geographies outside the US in Q4 2023. Topline results from the sunRIZE study are expected in the first half of 2025.
- RZ402, oral plasma kallikrein inhibitor to treat diabetic macular edema (DME)**
 - In December 2022, Rezolute announced the initiation of a Phase 2 study of RZ402 in patients with DME. This is a multi-center, randomized, double-masked, placebocontrolled, parallel-arm study 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. Study enrollment is ongoing, and the Company anticipates topline results from this study in the first quarter of 2024.

Fourth Quarter and Full Year Fiscal 2023 Financial Results

- Cash and cash equivalents totaled \$16.0 million and investments in marketable debt securities totaled \$102.3 million as of June 30, 2023.



- Research and development (R&D) expenses were \$10.9 million for the fourth quarter of fiscal 2023, compared to \$8.6 million for the same period in fiscal 2022. Full fiscal year 2023 R&D expenses were \$43.8 million, compared to \$32.5 million in fiscal year 2022. The increase from fiscal year 2022 to fiscal year 2023 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 \$3.3 million for the fourth quarter of fiscal 2023, compared to \$2.7 million for the same period in fiscal 2022. Full fiscal year 2023 G&A expenses were \$12.2 million, compared to \$9.4 million in fiscal year 2022. The increase from fiscal year 2022 to fiscal year 2023 was primarily due to higher personnel-related expenses, including employee compensation and stock-based compensation.
- Net loss was \$12.7 million for the fourth quarter of fiscal 2023, compared to \$9.4 million for the same period in fiscal 2022. Full year fiscal 2023 net loss was \$51.8 million compared to net loss of \$41.1 million for the fiscal year 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 or LinkedIn.

Forward-Looking Statements

The information provided herein contain “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as “anticipate,” “intend,” “plan,” “goal,” “seek,” “believe,” “project,” “estimate,” “expect,” “strategy,” “future,” “likely,” “may,” “should,” “will” and similar references to future periods. The “forward-looking statements” include, but are not limited to, statements regarding receiving results from the Phase 2 study of RZ402 in the first quarter of 2024, the ability of RZ358 to treat congenital hyperinsulinism, the timing of the release topline results from sunRIZE, and our ability to meet trial enrollment goals.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on Rezolute’s current beliefs, expectations and assumptions regarding the future of its businesses, results of and timing of clinical trials, financial condition and results of operations, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of Rezolute’s control. Rezolute’s actual results including the timing and results of clinical trials may differ materially from those indicated in the forward-looking statements. Therefore, you should not place undue reliance on any of these forward-looking statements. Important factors that could cause Rezolute’s actual results including the timing and results of clinical trials to differ materially from those indicated in the forward-looking statements are discussed or identified in Rezolute’s filings made with the U.S. Securities and Exchange Commission. Any forward-looking statements made by Rezolute in this information are based only on information currently available to Rezolute and speak only as of the date on which the statement is made. Rezolute undertakes no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise except as required by applicable law.



Investor:

Kimberly Minarovich
Argot Partners
rezolute@argotpartners.com
212-600-1902

Media:

media-relations@rezolutebio.com



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

	Three Months Ended June 30,		Year Ended June 30,	
	2023	2022	2023	2022
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 10,933	\$ 8,574	\$ 43,813	\$ 32,486
General and administrative	3,305	2,725	12,177	9,357
Total operating expenses	14,238	11,299	55,990	41,843
Loss from operations	(14,238)	(11,299)	(55,990)	(41,843)
Non-operating income (expense), net	1,510	1,876	4,203	783
Net loss	\$ (12,728)	\$ (9,423)	\$ (51,787)	\$ (41,060)
Net loss per common share				
Basic	\$ (0.25)	\$ (0.30)	\$ (1.01)	\$ (2.26)
Diluted	\$ (0.25)	\$ (0.37)	\$ (1.01)	\$ (2.32)
Weighted average number of common shares outstanding:				
Basic	51,410	31,429	51,188	18,197
Diluted	51,410	36,302	51,188	19,487
Condensed Consolidated Balance Sheets Data:				
Cash and cash equivalents			\$ 16,036	\$ 150,410
Investments in marketable debt securities			102,330	-
Working capital			99,710	149,642
Total assets			123,721	152,420
Accumulated deficit			(260,984)	(209,198)
Total stockholders' equity			123,721	149,471