

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): February 10, 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 February 10, 2023, Rezolute, Inc. issued a press release announcing its financial results for the second quarter ended December 31, 2022. 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
<u>99.1</u>	<u>Press Release, dated February 10, 2023</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.

DATE: February 10, 2023

REZOLUTE, INC.

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



Rezolute Reports Second Quarter Fiscal 2023 Results and Highlights Company Progress

Initiated Phase 2 proof-of-concept study of RZ402

Anticipate initiation of global Phase 3 clinical study for RZ358 in mid 2023

REDWOOD CITY, Calif., Feb. 10, 2023 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to transform the treatment paradigms of devastating metabolic diseases, today announced its financial results for the second quarter of fiscal 2023 ended December 31, 2022.

"The past quarter was marked by steady execution across our pipeline as we continue to advance toward our goal of bringing transformative therapies to patients across the spectrum of metabolic diseases," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "In December, we initiated a Phase 2 proof-of-concept study for RZ402 in patients with diabetic macular edema, and we are continuing to prepare for a global Phase 3 study for RZ358 for congenital hyperinsulinism."

Second Quarter Fiscal 2023 Financial Results

- Cash and cash equivalents totaled \$146.7 million as of December 31, 2022.
- Research and development (R&D) expenses were \$10.9 million for the second quarter of fiscal 2023, compared to \$9.5 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, driven primarily by higher headcount and equity award grants.
- General and administrative (G&A) expenses were \$3.4 million for the second quarter of fiscal 2023, compared to \$2.7 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, driven primarily by higher headcount and equity award grants.
- Net loss was \$13.6 million for the second quarter of fiscal 2023, compared to \$12.6 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 entirety by this cautionary statement.

Investor:

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

Media:

Ingrid Mezo
Canale Communications, Inc.
ingrid.mezo@canalecomm.com
301-473-2881



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

	Three Months Ended December 31,		Six Months Ended December 31,	
	2022	2021	2022	2021
	(unaudited)		(unaudited)	
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 10,945	\$ 9,452	\$ 18,649	\$ 15,226
General and administrative	3,447	2,697	5,961	4,563
Total operating expenses	14,392	12,149	24,610	19,789
Loss from operations	(14,392)	(12,149)	(24,610)	(19,789)
Non-operating income (expense), net	836	(444)	1,223	(640)
Net loss	<u>\$ (13,556)</u>	<u>\$ (12,593)</u>	<u>\$ (23,387)</u>	<u>\$ (20,429)</u>
Basic and diluted net loss per common share	<u>\$ (0.26)</u>	<u>\$ (0.80)</u>	<u>\$ (0.46)</u>	<u>\$ (1.69)</u>
Shares used to compute basic and diluted net loss per common share	<u>51,410</u>	<u>15,680</u>	<u>50,969</u>	<u>12,097</u>
			December 31,	June 30,
			2022	2022
			(unaudited)	
Condensed Consolidated Balance Sheets Data:				
Cash and cash equivalents			\$ 146,746	\$ 150,410
Working capital			141,293	149,642
Total assets			150,208	152,420
Accumulated deficit			(232,585)	(209,198)
Total stockholders' equity			141,265	149,471