

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 9, 2022

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

201 Redwood Shores Pkwy, Suite 315, Redwood City, CA 94065
(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 9, 2022, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 30, 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 November 9, 2022</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.

REZOLUTE, INC.

DATE: November 9, 2022

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

Rezolute Reports First Quarter Fiscal 2023 Results and Highlights Company Progress

Phase 2 proof-of-concept study of RZ402 expected to be initiated by the end of this year

REDWOOD CITY, Calif., Nov. 09, 2022 (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 first quarter of fiscal 2023 ended September 30, 2022.

"I am extremely pleased with our progress this year, having reported positive data from both our clinical programs, Phase 1b study of RZ402 for Diabetic Macular Edema and Phase 2b study of RZ358 for Congenital Hyperinsulinism (HI), as well as completing a \$130 million financing to advance both the molecules into the next phase of clinical studies," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We are on track to initiate a Phase 2 proof-of-concept study for RZ402 by the end of this year, and we are aligning with regulatory authorities in the U.S. and in Europe on next steps in our Phase 3 clinical program for RZ358."

Corporate and Clinical Highlights

- **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism**
 - o The results of the Phase 2b RIZE study of RZ358 in patients with congenital HI were presented at the 2022 Pediatric Endocrine Society Annual Meeting as well as at the 60th European Society for Paediatric Endocrinology (ESPE). RZ358 demonstrated good safety and tolerability across all doses with no study discontinuations or adverse drug reactions. Results exceeded expectations for correction of hypoglycemia, including a highly significant reduction of ~75% in hypoglycemia events by blood glucometer (BGM) as well as time in hypoglycemia by continuous glucose monitoring (CGM) at anticipated therapeutics doses.
- **RZ402, oral plasma kallikrein inhibitor to treat diabetic macular edema (DME)**
 - o Rezolute presented clinical data from its Phase 1b multiple-ascending dose (MAD) study of RZ402 in Diabetic Macular Edema (DME) in a podium presentation at The Retina Society 55th Annual Scientific Meeting. The data further validated and supported the potential for once daily oral dosing and enables Rezolute to initiate a Phase 2 proof-of-concept study by the end of the year.

First Quarter Fiscal 2023 Financial Results

- Cash and cash equivalents totaled \$154.3 million as of September 30, 2022.
- Research and development (R&D) expenses were \$7.7 million for the first quarter of fiscal 2023, compared to \$5.8 million for the same period in fiscal 2022. The increase was primarily due to increased spending in compensation and benefits, and clinical trial costs.

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- General and administrative (G&A) expenses were \$2.5 million for the first quarter of fiscal 2023, compared to \$1.9 million for the same period in fiscal 2022. The increase was primarily due to an increase in share-based compensation expense.
 - Net loss was \$9.8 million for the first quarter of fiscal 2023, compared to \$7.8 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:

Chiti Chopra
 Director, Corporate Strategy
Investor-relations@rezolutebio.com
 408-606-0789

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

Media:

Ingrid Mezo
 Canale Communications, Inc.

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

	Three Months Ended	
	September 30,	
	2022	2021
Condensed Consolidated Statements of Operations Data:		
Operating expenses:		
Research and development	\$ 7,704	\$ 5,774
General and administrative	2,514	1,866
Total operating expenses	<u>10,218</u>	<u>7,640</u>
Loss from operations	(10,218)	(7,640)
Non-operating income (expense), net	387	(196)
Net loss	<u>\$ (9,831)</u>	<u>\$ (7,836)</u>
Basic and diluted net loss per common share	<u>\$ (0.19)</u>	<u>\$ (0.92)</u>
Shares used to compute basic and diluted net loss per common share	<u>50,528</u>	<u>8,513</u>
	September 30,	June 30,
	2022	2022
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	\$ 154,322	\$ 150,410
Working capital	153,198	149,642
Total assets	155,988	152,420
Accumulated deficit	(219,029)	(209,198)
Total stockholders' equity	153,090	149,471