
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 12, 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.)

201 Redwood Shores Pkwy, Suite 315, 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 May 12, 2022, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 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 May 12, 2022</u>
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: May 12, 2022

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



Rezolute Reports Third Quarter Fiscal 2022 Financial Results and Highlights Company Progress

Announced a \$130 million registered direct offering and concurrent private placement

Positive topline results from Phase 2b RIZE study of RZ358 exceeded expectations and demonstrated highly significant reduction in hypoglycemia events, ~75% at anticipated therapeutic doses

Positive data from Phase 1b multiple-ascending dose study of RZ402 enable Phase 2 proof-of-concept study initiation later this year

REDWOOD CITY, Calif., May 12, 2022 (GLOBE NEWSWIRE) – Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company dedicated to developing transformative therapies with the potential to disrupt current treatment paradigms for devastating metabolic diseases, today announced its financial results for the third quarter of fiscal 2022 ended March 31, 2022.

"The first half of 2022 has been dynamic and transformative for us, as we have announced positive clinical results for both RZ358 as well as RZ402," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "I am particularly pleased that the strength of our pipeline has been recognized by the investment community culminating in the \$130 million financing that we completed earlier this month. The injection of capital will fund our upcoming program milestones, including Phase 3 for RZ358 and a Phase 2 proof of concept study for RZ402."

Business Highlights

- **Financing Update**
 - o In May, Rezolute raised gross proceeds of \$130 million in a registered direct offering and concurrent private placement backed by notable growth and life science investors including, amongst others, Federated Hermes Kaufmann Funds, Stonepine Capital Management, Medical Strategy GmbH, Acuta Capital Partners, Adage Capital Partners LP, CAM Capital, Janus Henderson Investors, Sphera Healthcare, and Vivo Capital.
- **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism**
 - o In a late-breaking oral presentation at the Pediatric Endocrine Society 2022 Annual Meeting, Dr. Paul Thornton presented results from the Phase 2b RIZE study of RZ358 in patients with congenital hyperinsulinism (HI). RZ358 demonstrated good safety and tolerability across all doses with no study discontinuations or adverse drug reactions. Predictable and dose-dependent exposures with a clear dose-response was observed. 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. These data are Phase 3 enabling and demonstrate the potential for RZ358 to be used as a monotherapy as well as a potential universal therapy for all forms of hyperinsulinism.



- **RZ402, oral plasma kallikrein inhibitor to treat diabetic macular edema (DME)**
 - o Positive topline data from the Phase 1b multiple-ascending dose study of RZ402 were announced in February. Results showed that RZ402 was generally safe and well-tolerated without dose-limiting toxicities, including at higher doses than previously tested in the SAD study. There were no serious adverse events, adverse drug reactions or identified risks. Results demonstrated dose-dependent increases in systemic exposures, with repeat-dosing to steady-state resulting in the highest concentrations of RZ402 explored to date. These data further validate and support the potential for once daily oral dosing and enable the company to initiate a Phase 2 proof-of-concept study later this year.
- **Rare Disease Company Coalition**
 - o In March, Rezolute announced its membership as part of the [Rare Disease Company Coalition](#), an alliance of life science companies committed to discovering, developing, and delivering rare disease treatments for the patients they collectively serve.

Third Quarter Fiscal 2022 Financial Results

- Cash and cash equivalents totaled \$63.4 million as of March 31, 2022.
- Research and development (R&D) expenses were \$8.7 million for the three months ended March 31, 2022, compared to \$3.8 million for the same period in 2021. The increase was primarily due to a licensing payment for RZ358, increased spending in clinical trial costs, manufacturing costs, and compensation and benefits.
- General and administrative (G&A) expenses were \$2.1 million for the three months ended March 31, 2022, compared to \$1.7 million for the same period in 2021. The increase was primarily attributable to an increase in share-based compensation expense due to options granted to employees in the quarter.
- Net loss was \$11.2 million, or \$0.65 per share for the three months ended March 31, 2022, compared to \$3.7 million, or \$0.44 per share for the same period in 2021.

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.

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

Three Months Ended		Nine Months Ended	
March 31,		March 31,	
2022	2021	2022	2021
(unaudited)		(unaudited)	

Condensed Consolidated Statements of Operations Data:

Operating expenses:

Research and development	8,686	3,758	23,912	10,598
General and administrative	2,068	1,725	6,632	5,660
Total operating expenses	10,754	5,483	30,544	16,258
Loss from operations	(10,754)	(5,483)	(30,544)	(16,258)
Non-operating income (expense), net	(454)	1,788	(1,093)	1,846
Net loss	<u>\$ (11,208)</u>	<u>\$ (3,695)</u>	<u>\$ (31,637)</u>	<u>\$ (14,412)</u>
Basic and diluted net loss per common share	<u>\$ (0.65)</u>	<u>\$ (0.44)</u>	<u>\$ (2.30)</u>	<u>\$ (1.94)</u>
Shares used to compute basic and diluted net loss per common share	<u>17,218</u>	<u>8,352</u>	<u>13,748</u>	<u>7,445</u>

	<u>March 31,</u> <u>2022</u> <u>(unaudited)</u>	<u>June 30,</u> <u>2021</u>
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	\$ 63,416	\$ 41,047
Working capital	61,453	40,025
Total assets	69,573	42,609
Long term debt, net of discount ⁽¹⁾	14,286	13,968
Accumulated deficit	(199,775)	(168,138)
Total stockholders' equity	51,907	26,099

(1) In April 2021, we entered into a \$30.0 million Loan Agreement with SLR and certain other Lenders. \$15.0 million term A loan was funded on April 14, 2021.