

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 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.)

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 February 9, 2022, Rezolute, Inc. issued a press release announcing its financial results for the second quarter ended December 31, 2021. 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 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: February 9, 2022

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

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press Release, dated February 9, 2022</u>
104	Cover Page Interactive Data File (embedded as Inline XBRL document)



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

Topline results from RZ358 Phase 2b and RZ402 Phase 1b studies expected before the end of Q1 2022

REDWOOD CITY, Calif., February 9, 2022 (GLOBE NEWSWIRE) – Rezolute, Inc. (Nasdaq: RZLT), a clinical-stage biopharmaceutical company developing transformative therapies for metabolic diseases associated with chronic glucose imbalance, today announced its financial results for the second quarter of fiscal 2022 ended December 31, 2021.

“We have maintained excellent momentum and are on track to report topline data before the end of next month for both of our lead clinical programs,” said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute.

Business Highlights

- **Financing Update**
 - o In Q4 of 2021, Rezolute raised gross proceeds of \$56 million in a public offering of common stock, and of pre-funded warrants, and in a concurrent registered direct offering.
- **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism**
 - o Topline results from the Phase 2b RIZE study of RZ358 are on track and anticipated before the end of March 2022.
- **RZ402, oral plasma kallikrein inhibitor to treat diabetic macular edema (DME)**
 - o Topline results from the Phase 1b multiple ascending dose study of RZ402 are also on track and anticipated before the end of March 2022.

Second Quarter Fiscal 2022 Financial Results

- Cash and cash equivalents totaled \$77.4 million as of December 31, 2021.
- Research and development (R&D) expenses were \$9.5 million for the second quarter of fiscal 2022, compared to \$4.5 million for the same period in fiscal 2021. The increase was primarily due to increased spending in clinical trial costs, manufacturing costs, and compensation and benefits.
- General and administrative (G&A) expenses were \$2.7 million for the second quarter of fiscal 2022, compared to \$2.7 million for the same period in fiscal 2021.
- Net loss was \$12.6 million, or \$0.80 per share for the second quarter of fiscal 2022, compared to \$7.1 million, or \$0.88 per share for the same period in fiscal 2021.



About Rezolute, Inc.

Rezolute is developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company’s lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (HI), a rare pediatric endocrine disorder. The Company 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, Inc. 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 the Company, 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.

Investor Contact

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

Media Contact

Kelly North
Canale Communications, Inc.
Kelly.north@canalecomm.com
(425) 213-0429



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

	Three Months Ended		Six Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
	(unaudited)		(unaudited)	
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	9,452	4,496	15,226	6,840
General and administrative	2,697	2,656	4,563	3,935
Total operating expenses	<u>12,149</u>	<u>7,152</u>	<u>19,789</u>	<u>10,775</u>
Loss from operations	(12,149)	(7,152)	(19,789)	(10,775)
Non-operating income (expense), net	(444)	55	(640)	58
Net loss	<u>\$ (12,593)</u>	<u>\$ (7,097)</u>	<u>\$ (20,429)</u>	<u>\$ (10,717)</u>
Basic and diluted net loss per common share	<u>\$ (0.80)</u>	<u>\$ (0.88)</u>	<u>\$ (1.69)</u>	<u>\$ (1.54)</u>
Shares used to compute basic and diluted net loss per common share	<u>15,680</u>	<u>8,045</u>	<u>12,097</u>	<u>6,956</u>

	December 31,		June 30,	
	2021		2021	
	(unaudited)			
Condensed Consolidated Balance Sheets Data:				
Cash and cash equivalents	\$	77,403	\$	41,047
Working capital		71,653		40,025
Total assets		83,405		42,609
Long term debt, net of discount ⁽¹⁾		14,178		13,968
Accumulated deficit		(188,567)		(168,138)
Total stockholders' equity		62,265		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.