

**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 15, 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 September 15, 2022, Rezolute, Inc. issued a press release announcing its financial results for the fourth quarter and fiscal year ended June 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.*

<u>Exhibit No.</u>	<u>Description</u>
<a href="#">99.1</a>	<a href="#">Press Release, dated September 15, 2022</a>
104	Cover Page Interactive Data File (formatted as inline XBRL)

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**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 15, 2022

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

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## Rezolute Reports Fourth Quarter and Full Year Fiscal 2022 Results and Highlights Company Progress

*Announced a \$130 million registered direct offering and concurrent private placement priced at-the-market*

*Late-breaking oral presentation from Phase 2b RIZE study of RZ358 presented at ESPE 2022*

*Phase 2 proof-of-concept study of RZ402 expected to be initiated later this year*

**REDWOOD CITY, Calif., September 15, 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 fourth quarter and full fiscal year ended June 30, 2022.

“This quarter marked steady progress as we continue to drive our clinical programs forward, including RZ358 for congenital hyperinsulinism and RZ402 for diabetic macular edema,” said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. “With the \$130 million financing that we completed, we are well-capitalized to advance RZ358 into a Phase 3 trial and to initiate a Phase 2 proof-of-concept study for RZ402. We believe these candidates hold the potential to create a new standard of care for patient populations in need of better therapeutic options.”

### Corporate and Clinical Highlights

- **Financing Update**
    - o Rezolute raised gross proceeds of \$130 million in a registered direct offering and concurrent private placement backed by notable growth and life science investors.
  - **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism**
    - o The results of the Phase 2b RIZE study of RZ358 in patients with congenital hyperinsulinism (HI) were revealed in a late-breaking oral presentation at the 2022 Pediatric Endocrine Society Annual Meeting in May and discussed by management in a conference call following the presentation. 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. Rezolute also presented additional data from the RIZE study at the 60<sup>th</sup> European Society for Paediatric Endocrinology (ESPE) meeting this month.
  - **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 earlier this year. These data further validate and support the potential for once daily oral dosing and enable Rezolute to initiate a Phase 2 proof-of-concept study in the fourth calendar quarter of this year.
  - **Key leadership announcement**
    - o Rezolute announced the promotion of Brian Roberts, M.D., previously Senior Vice President and Head of Clinical Development, to Chief Medical Officer of Rezolute. Dr. Roberts joined Rezolute in 2017 as Vice President of Clinical Development and a member of the founding management team.
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#### Fourth Quarter and Full Year Fiscal 2022 Financial Results

- Cash and cash equivalents totaled \$150.4 million as of June 30, 2022.
- Research and development (R&D) expenses were \$8.6 million for the fourth quarter of fiscal 2022, compared to \$4.4 million for the same period in fiscal 2021. Full fiscal year 2022 R&D expenses were \$32.5 million, compared to \$15.0 million in fiscal year 2021. The increase from fiscal year 2021 to fiscal year 2022 was primarily due to increased spending for clinical trial activities, manufacturing costs, compensation and benefits and an increase in licensing payments.
- General and administrative (G&A) expenses were \$2.7 million for the fourth quarter of fiscal 2022, compared to \$2.2 million for the same period in fiscal 2021. Full fiscal year 2022 G&A expenses were \$9.4 million, compared to \$7.9 million in fiscal year 2021. The increase from fiscal year 2021 to fiscal year 2022 were primarily due to increased spending in professional services.
- Net loss was \$9.4 million for the fourth quarter of fiscal 2022, compared to \$6.5 million for the same period in fiscal 2021. Full year fiscal 2022 net loss was \$41.1 million compared to net loss of \$20.9 million for the fiscal year 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](http://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](http://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)  
(Unaudited)

	Three Months Ended June 30,		Year Ended June 30,	
	2022	2021	2022	2021
<b>Condensed Consolidated Statements of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 8,574	\$ 4,389	\$ 32,486	\$ 14,987
General and administrative	2,725	2,247	9,357	7,907
Total operating expenses	11,299	6,636	41,843	22,894
Loss from operations	(11,299)	(6,636)	(41,843)	(22,894)
Non-operating income, net	1,876	146	783	1,992
Net loss	\$ (9,423)	\$ (6,490)	\$ (41,060)	\$ (20,902)
Net loss per common share				
Basic	\$ (0.30)	\$ (0.78)	\$ (2.26)	\$ (2.72)
Diluted	\$ (0.37)	\$ (0.78)	\$ (2.32)	\$ (2.72)
Weighted average number of common shares outstanding:				
Basic	31,429	8,352	18,197	7,671
Diluted	36,302	8,352	19,487	7,671
<b>Condensed Consolidated Balance Sheets Data:</b>				
Cash and cash equivalents			\$ 150,410	\$ 41,047
Working capital			149,642	40,025
Total assets			152,420	42,609
Long term debt, net of discount			—	13,968
Accumulated deficit			(209,198)	(168,138)
Total stockholders' equity			149,471	26,099