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 17, 2021

REZOLUTE, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**000-54495**	**27-3440894**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 17, 2021, Rezolute, Inc. issued a press release announcing its financial results for the third quarter ended March 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
99.1	Press Release, dated May 17, 2021

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 17, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated May 17, 2021

Exhibit 99.1

Rezolute Reports Third Quarter Fiscal 2021 Financial Results and Highlights Recent Company Progress

REDWOOD CITY, Calif., May 17, 2021 (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 fiscal third quarter ended March 31, 2021.

"We continue to advance the clinical development of our pipeline candidates, RZ358 and RZ402, with several milestones expected this year," said Nevan Elam, Chief Executive Officer of Rezolute. "Highly encouraging topline results from our Phase 1 study of RZ402 support oral daily dosing for the treatment of diabetic macular edema, and we are on track to initiate a repeat-dose Phase 1b trial in the third quarter of 2021."

Recent Business Highlights

- **Worldwide enrollment continues in the Phase 2b (RIZE) study of RZ358 for the treatment of patients with congenital hyperinsulinism (CHI) –**Enrollment is ongoing in the Phase 2b RIZE study of RZ358 for the treatment of CHI, with top line data expected in the second half of 2021. RZ358 is designed to increase glucose in the bloodstream of CHI patients by reducing insulin activity at its receptor.
- **Completed the Phase 1 study of RZ402 for the treatment of diabetic macular edema (DME) –**In May 2021, Rezolute announced topline results from its first-in-human Phase 1a clinical study of RZ402, the Company's investigational oral plasma kallikrein inhibitor (PKI), for the treatment DME. Study results demonstrated the potential for once daily oral dosing and support the advancement of developmental activities toward Phase 2, including a Phase 1b multiple ascending dose study to be initiated in the third quarter of 2021.
- **Leading rare disease experts Appointed to the Board of Directors**– In March 2021, Rezolute announced the appointments of Wladimir Hogenhuis, M.D., MBA, and Nerissa C. Kreher, M.D., M.S., MBA to its Board of Directors.

Third Quarter Fiscal 2021 Financial Results

- Cash and cash equivalents totaled $32.0 million as of March 31, 2021.
- Research and development (R&D) expenses total $3.8 million in the third quarter of 2021 compared to $3.7 million in the same quarter of last year.
- General and administrative (G&A) expenses were $1.7 million in the third quarter of 2021 compared to $1.3 million in the prior period last year. The increase was primarily due to an increase in professional fees.
- Net loss was $3.7 million, or $0.44 per share, for the third quarter of fiscal 2021 compared to net loss of $5.0 million, or $0.86 per share, for the same period in fiscal 2020.

About Rezolute, Inc.

Rezolute is advancing transformative therapies for metabolic diseases associated with chronic glucose imbalance. The Company's lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (CHI), 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/Media Contact
rezolute@argotpartners.com

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

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
	(unaudited)			
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	3,758	3,733	10,598	12,005
General and administrative	1,725	1,337	5,660	4,964
Total operating expenses	5,483	5,070	16,258	16,969
Loss from operations	(5,483)	(5,070)	(16,258)	(16,969)
Non-operating income - interest and other	1,788	30	1,846	183
Net loss	$ (3,695)	$ (5,040)	$ (14,412)	$ (16,786)
Basic and diluted net loss per common share	$ (0.44)	$ (0.86)	$ (1.94)	$ (2.93)

Shares used to compute basic and diluted net loss per common share	8,352	5,866	7,445	5,719

	March 31, 2021 (unaudited)	June 30, 2020
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 31,989	$ 9,955
Working capital	28,607	7,292
Total assets	32,933	10,965
License fees payable to Xoma (1)	-	1,809
Accumulated deficit	(161,648)	(147,236)
Total stockholders' equity	29,132	7,365

(1) In October 2020, we completed a private placement of equity securities for gross proceeds of $41.0 million, resulting in acceleration of the entire $1.4 million outstanding obligation shown above and we paid it on October 23, 2020.