

**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 12, 2021

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 November 12, 2021, Rezolute, Inc. issued a press release announcing its financial results for the first quarter ended September 30, 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.*

| <u>Exhibit No.</u> | <u>Description</u> |
|----------------------|--|
| 99.1 | Press Release, dated November 12, 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: November 12, 2021

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

EXHIBIT INDEX

Exhibit No.

Description

[99.1](#)

[Press Release, dated November 12, 2021](#)

Rezolute Reports First Quarter Fiscal 2022 Financial Results and Highlights Recent Company Progress

REDWOOD CITY, Calif., November 12, 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 first quarter of fiscal 2022 ended September 30, 2021.

“This has been a productive quarter of execution for Rezolute, with steady clinical advancement of our lead pipeline candidates, RZ358 and RZ402, in Phase 2b and Phase 1b development, respectively,” said Nevan Elam, Chief Executive Officer and Founder of Rezolute. “We look forward to announcing topline data for both programs in Q1 of 2022. Additionally, with a strengthened balance sheet following our recent offering, raising \$55 million in gross proceeds, we have extended our cash runway and are well-positioned to continue to execute on our key clinical milestones.”

Recent Business Highlights

- **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism (HI)** – Enrollment is ongoing in the Phase 2b RIZE study of RZ358 for the treatment of congenital HI. The Company expects to report topline results in Q1 of 2022.
- **European Society for Paediatric Endocrinology (ESPE) 2021** – Rezolute presented results from a natural history study designed to highlight the utility of continuous glucose monitors (CGM) and to quantify the extent of hypoglycemia in congenital HI patients on standard of care therapies.
- **RZ402, oral PKI for the treatment of diabetic macular edema (DME)** – A Phase 1b multiple ascending dose study, initiated in August 2021, is progressing as expected, with topline data expected in Q1 of 2022.
- **Financing Update** – In October of 2021, Rezolute completed an underwritten public offering of 6,030,847 shares of its common stock at a public offering price of \$6.50 per share and of pre-funded warrants to purchase 1,661,461 shares of its common stock at a public price of \$6.49 and completed a registered direct offering of 769,231 shares of its common stock at a public price of \$6.50 per share. The gross proceeds of \$55 million will be used to support clinical trial and program development activities.

First Quarter Fiscal 2022 Financial Results

- Cash and cash equivalents totaled \$37.3 million as of September 30, 2021.
 - Research and development (R&D) expenses were \$5.8 million for the first quarter of fiscal 2022, compared to \$2.3 million for the same period in fiscal 2021. The increases from fiscal year 2021 to fiscal year 2022 were primarily due to increased spending in compensation and benefits, and clinical trial costs.
 - General and administrative (G&A) expenses were \$1.9 million for the first quarter of fiscal 2022, compared to \$1.3 million for the same period in fiscal 2021. The increases from fiscal year 2021 to fiscal year 2022 were primarily due to professional fees associated with corporate development activities, consulting services, and strategic financial advisory services along with an increase in share-based compensation expense.
 - Net loss was \$7.8 million, or \$0.92 per share for the first quarter of fiscal 2022, compared to \$3.6 million, or \$0.62 per share for the same period in fiscal 2021.
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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.

Media and Investor Contact

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212-600-1902

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

| | Three Months Ended | |
|--|---------------------------|-------------------|
| | September 30, | |
| | 2021 | 2020 |
| | (unaudited) | |
| Condensed Consolidated Statements of Operations Data: | | |
| Operating expenses: | | |
| Research and development | 5,774 | 2,344 |
| General and administrative | 1,866 | 1,279 |
| Total operating expenses | <u>7,640</u> | <u>3,623</u> |
| Loss from operations | (7,640) | (3,623) |
| Non-operating income (expense), net | (196) | 3 |
| Net loss | <u>\$ (7,836)</u> | <u>\$ (3,620)</u> |
| Basic and diluted net loss per common share | <u>\$ (0.92)</u> | <u>\$ (0.62)</u> |
| Shares used to compute basic and diluted net loss per common share | <u>8,513</u> | <u>5,867</u> |

| | September 30, | June 30, |
|--|----------------------|-----------------|
| | 2021 | 2021 |
| | (unaudited) | |
| Condensed Consolidated Balance Sheets Data: | | |
| Cash and cash equivalents | \$ 37,292 | \$ 41,047 |
| Working capital | 35,747 | 40,025 |
| Total assets | 38,760 | 42,609 |
| Long term debt, net of discount ⁽¹⁾ | 14,071 | 13,968 |
| Accumulated deficit | (175,974) | (168,138) |
| Total shareholders' equity | 21,559 | 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.