

**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 10, 2021

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

Delaware
(State or Other Jurisdiction
of Incorporation)

000-54495
(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 10, 2021, Rezolute, Inc. issued a press release announcing its financial results for the quarter ended December 31, 2020. 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 February 10, 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: February 10, 2021

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

EXHIBIT INDEX

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|----------------------|--|
| 99.1 | Press Release, dated February 10, 2021 |

Rezolute Reports Second Quarter Fiscal 2021 Financial Results

REDWOOD CITY, Calif., February 10, 2021 (GLOBE NEWSWIRE) – Rezolute, Inc. (Nasdaq: RZLT), today announced its financial results for the quarter ended December 31, 2020.

Recent Business Highlights

- **Phase 2b study of RZ358 continues to enroll congenital hyperinsulinism (HI) patients worldwide** –The RIZE Phase 2b study of RZ358 for the treatment of congenital HI continues to enroll patients, with study completion expected in the second half of 2021. RZ358 is an allosteric modulator of the insulin receptor being developed as a treatment for all forms of congenital HI.
- **Initiation of Phase 1 study of RZ402** – In January 2021, Rezolute announced initiation of dosing in a Phase 1 clinical study of oral plasma kallikrein inhibitor RZ402 in healthy volunteers. RZ402 is a potential first-in-class therapy being investigated as a once-daily oral treatment for diabetic macular edema. Study completion is expected in the first half of 2021.

Second Quarter Fiscal 2021 Financial Results

- Net loss was \$7.1 million, or \$0.88 per share, for the second quarter of fiscal 2021 compared to net loss of \$6.7 million, or \$1.14 per share, for the same period in fiscal 2020.
- Cash and cash equivalents totaled \$37.0 million as of December 31, 2020. This includes \$37.5 million in net proceeds from an October 2020 private placement financing.

About Rezolute, Inc.

Rezolute is advancing targeted therapies for rare, metabolic, and life-threatening diseases. Its lead product candidate, RZ358, is in Phase 2b development as a potential treatment for congenital hyperinsulinism (HI), a rare pediatric endocrine disorder. Its pipeline also includes RZ402, an orally available plasma kallikrein inhibitor in Phase 1 development as a potential treatment for 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.

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Rezolute, Inc.

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

| | Three Months Ended December 31, | | Six Months Ended December 31, | |
|--|------------------------------------|------------|----------------------------------|-------------|
| | 2020 | 2019 | 2020 | 2019 |
| (unaudited) | | | | |
| Condensed Consolidated Statements of Operations Data: | | | | |
| Operating expenses: | | | | |
| Research and development | 4,496 | 5,038 | 6,840 | 8,272 |
| General and administrative | 2,656 | 1,682 | 3,935 | 3,627 |
| Total operating expenses | 7,152 | 6,720 | 10,775 | 11,899 |
| Loss from operations | (7,152) | (6,720) | (10,775) | (11,899) |
| Non-operating income - interest and other | 55 | 54 | 58 | 153 |
| Net loss | \$ (7,097) | \$ (6,666) | \$ (10,717) | \$ (11,746) |

| | | | | |
|--|-----------|-----------|-----------|-----------|
| Basic and diluted net loss per common share | \$ (0.88) | \$ (1.14) | \$ (1.54) | \$ (2.08) |
| Shares used to compute basic and diluted net loss per common share | 8,045 | 5,866 | 6,956 | 5,646 |

| | |
|---------------------|-----------------|
| December 31, | June 30, |
| 2020 | 2020 |
| (unaudited) | |

Condensed Consolidated Balance Sheets Data:

| | | |
|---|-----------|-----------|
| Cash and cash equivalents | \$ 37,600 | \$ 9,955 |
| Working capital | 35,419 | 7,292 |
| Total assets | 38,902 | 10,965 |
| License fees payable to Xoma ⁽¹⁾ | - | 1,809 |
| Accumulated deficit | (157,953) | (147,236) |
| Total stockholders' equity | 35,886 | 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.