

**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): January 10, 2025

**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.)

275 Shoreline Drive, Suite 500, 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 7.01 Regulation FD Disclosure.**

On January 10, 2025, Rezolute, Inc. (the "Company") posted a pre-recorded video to detail a patient's participation in the Company's Phase 2 clinical study. The webcast is available <https://rezolutestage.wpengine.com/for-patients/>, and the transcript of the video is included as Exhibit 99.1 hereto.

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.

The transcript contains forward looking statements. 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," "prove," "potential," "seek," "strive," "try," or future or conditional verbs such as "predict," "could," "may," "likely," "should," "will," "would," or similar expressions. The Company's ability to predict results or the actual effects of the Company's plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers of the transcript and viewers of the testimonial are cautioned not to place undue reliance on these forward-looking statements, which speak only as an individual patient. Except as required by applicable law or regulation, the Company 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 the Company's filings with the SEC, including the Risk Factors contained in the Company'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).

**Item 9.01 Financial Statements and Exhibits.**

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Rezolute, Inc. Transcript of the Video, dated January 10, 2025</u>
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: January 14, 2025

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

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### Rezolute Film Transcript

Ersodetug is an investigational drug candidate. The FDA has not determined that ersodetug is safe or effective. No indication(s), warnings, precautions, adverse reactions, dosage or administration information for ersodetug have been approved by the FDA. This video depicts the favorable results of ersodetug use for a single patient. It is not intended to guarantee or promote that ersodetug will provide similar results for other subjects participating in the ersodetug Phase III clinical trial or Expanded Access Program.

This video, 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,” “prove,” “potential,” “seek,” “strive,” “try,” or future or conditional verbs such as “predict,” “could,” “may,” “likely,” “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. Viewers are cautioned not to place undue reliance on these forward-looking statements, which speak only as an individual patient. 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 our 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. This video shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state or other jurisdiction.

#### **Dr Davelyn Hood**

Hi, my name is Dr. Davelyn Hood, and I head Medical and Patient Affairs at Rezolute.

I am also a congenital HI mom to an amazing young man who was born in 2000 with severe, diffuse HI requiring a subtotal pancreatectomy at just 2 weeks of age when available therapies (the same that are available today) failed to adequately manage his life-threatening hypoglycemia.

Following many years of volunteering with an international patient advocacy group, I joined the amazing team at Rezolute to help move forward ersodetug, a new and promising first-in-class treatment for HI that is now being studied in a global Phase 3 clinical trial.

The story you’re about to watch is just one of a number of congenital HI patients and families who live in a shadow of fear because their daily lives are profoundly disrupted by persistent, unmanageable hypoglycemia - and how ersodetug is demonstrating the potential to safely reduce hypoglycemia while significantly improving the patients’ quality of life.

Paula participated in our last Phase 2 clinical study at the age of 10. At the time of filming of this video, Paula has been on ersodetug for nearly 2.5 years through our Expanded Access Program.

As Rezolute continues to study ersodetug as a potential treatment for all forms of hyperinsulinism, we are hopeful many more lives may be positively impacted, just like Paula’s.

#### **Paula’s Story**

##### **Paula:**

There was no hanging out with friends, I couldn’t go to the pool, or go to sleep at a friend’s house. I couldn’t really do anything, not even go out alone in the town for a few hours.

This illness makes me have low blood sugar and when my sugar drops my pancreas keeps producing insulin, which makes it drop even faster.

I often get sugar drops, especially if I’ve eaten a lot of sugar, which then causes a rise, and then that rise turns into a strong drop.

When I have a drop, I get headaches and I feel like everything is spinning, I get really dizzy.

The worst part of having hyperinsulinism is that it often limits me. Before the medication, I was limited so much in the things I could do.

##### **Cristina:**

I remember when they finally said it was hyperinsulinism, they were actually very quick (at diagnosing the disease) at the hospital when she was born, so I asked, well, what does this mean for the future?

You imagine that when your baby is born you go home, and you start a new life with everything you imagined. And then suddenly, it’s like ‘boom’, and all of that shatters.

Every week, every single week, I’d have to pick her up from school once or twice because of a sugar drop, or I’d have to go with her on school trips, or change all our plans, even things like Christmas Day because Paula had a sugar drop.

Cancel trips, cancel dinner plans, cancel everything, because I’d be on my way to meet friends, and suddenly she would have a drop in the car.

Fear, the fear is that she might not be the same. That she might not be the same. Because despite everything, she’s always been super happy, super curious, asking questions.

And what if that’s no longer there? What if it’s gone forever?

It’s like this constant shadow, this fear. What if this time she doesn’t recover? What if it’s done some damage to her brain? What if she doesn’t come back from this one? What if she’s not the same Paula anymore? It’s a shadow that’s always there.

The decision to join the trial came together because of several things, Paula had entered a really complicated time when it came to keeping her sugar stable. It was a very tough

time.

But wow the medication worked super well from the beginning, and we said ok let's just keep going and going.

Because thanks to this, she can have a normal life.

**Paula:**

Honestly, I do hope to keep taking the medication because it works well for me. I feel much better. Not only can I do so much more stuff, but I also feel much better.

Simply the fact of having to eat that much, I would have to eat and then eat again and again which was usually the case.

My life has changed so much with the medication. For example, on trips, I don't have to check my sugar anywhere near as much, and at school, the machine doesn't beep as much, which distracted my classmates.

And so now I don't need to be constantly drinking juice and stuff like that.

**Cristina:**

Before, she couldn't swim for more than half an hour in the pool, and now she can swim for four hours without her sugar dropping. Before, after every half hour on the bike, we had to stop.

Now, we go 2, 3, 4 hours on the bike and she's fine. Before, she couldn't stay over at friends' houses because I was afraid, and the people she would stay with were also afraid of her sugar dropping.

Now she's started going to dinner with her group of friends. And she has a better quality of life, a normal teenage life, that she wouldn't have had without this medication.

It's not that I imagine it, it's that I know, that if Paula stops taking this medication, we're going to go back to the same situation.

Paula has a great quality of life thanks to this medication. And I think that if Paula continues to be the Paula that she is now, she's going to help a lot of people.

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