

September 17, 2025



# Rezolute Reports Fourth Quarter and Full Year Fiscal 2025 Financial Results and Provides Business Update

REDWOOD CITY, Calif., Sept. 17, 2025 (GLOBE NEWSWIRE) -- **Rezolute, Inc. (Nasdaq: RZLT)** (“**Rezolute**” or the “**Company**”), a late-stage rare disease company focused on treating hypoglycemia caused by hyperinsulinism, today reported financial results and provided a business update for the fourth quarter and full fiscal year ended June 30, 2025.

“We have made substantial progress this year across our two indications for ersodetug in both congenital and tumor hyperinsulinism,” said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. “We believe that FDA alignment on a streamlined Phase 3 trial in tumor hyperinsulinism is further recognition of ersodetug’s broad applicability across multiple forms of hyperinsulinism and highlights both the urgent need and the transformative potential of our therapy for patients and families living with this condition. We remain on track to report topline results from the sunRIZE trial in December and look forward to progressing towards potential commercialization.”

## Recent Pipeline Progress and Anticipated Milestones

### Congenital Hyperinsulinism (HI)

- Completed enrollment in sunRIZE, a Phase 3, multicenter, double-blind, randomized, controlled safety and efficacy registrational study of ersodetug for the treatment of congenital HI.
  - Exceeded enrollment with 62 participants enrolled, including approximately 15 percent from U.S. sites.
  - Topline results expected in December 2025.
- Presented “Preliminary Patient Demographics And Baseline Characteristics From A Phase 3 Study (sunRIZE) Of Ersodetug For Hypoglycemia Due To Congenital Hyperinsulinism: Trial In Progress” at the Annual Meeting of the Endocrine Society (ENDO 2025). The enrolled population is comparable to the Phase 2 RIZE study and include:
  - 3.4y average age: 35% <2 years old
  - 15 (average) hypoglycemia events/week
  - 19% daily percent time in hypoglycemia
  - 95% taking  $\geq 1$  SOC treatments

### Tumor HI

- In August 2025, the Company achieved alignment with FDA on a significantly streamlined clinical development path for its ongoing Phase 3 study (upLIFT) of ersodetug for the treatment tumor HI.

- The truncated study will include as few as 16 participants and will be limited to the single-arm open-label portion of the upLIFT study, removing the need to conduct a double-blind randomized placebo-controlled trial.
- Enrollment is underway and topline results are expected in the second half of 2026.

## **Corporate Updates**

- In August 2025 the Company appointed Dr. Sunil Karnawat as Chief Commercial Officer.
  - Dr. Karnawat has over 25 years of experience in global commercialization of biopharmaceuticals and medical devices and will spearhead launch strategy and global market readiness for ersodetug.
  - Before joining Rezolute, Dr. Karnawat served as a Vice President at Cytokinetics and Ultragenyx. At Ultragenyx, he was responsible for leading key commercial functions in launching four ultra-rare disease products, including Crysvida.

## **Fourth Quarter and Full Year Fiscal 2025 Financial Results**

Cash, cash equivalents and investments in marketable securities were \$167.9 million as of June 30, 2025, compared with \$127.1 million as of June 30, 2024.

Research and development (R&D) expenses were \$20.9 million for the fourth quarter of fiscal 2025, compared with \$19.1 million for the same period a year ago. Full fiscal year 2025 R&D expenses were \$61.5 million, compared to \$55.7 million in fiscal year 2024. The increase from fiscal year 2024 to fiscal year 2025 was primarily due to (i) increased expenditures in clinical trial activities, (ii) manufacturing costs for ersodetug, and (iii) higher employee-related expenses, which included employee compensation and stock-based compensation.

General and administrative (G&A) expenses were \$5.0 million for the fourth quarter of fiscal 2025, compared with \$4.0 million for the same period a year ago. Full fiscal year 2025 G&A expenses were \$18.4 million, compared to \$14.7 million in fiscal year 2024. The increase was primarily attributable to professional fees and employee-related expenses due to increased headcount.

Net loss was \$24.4 million for the fourth quarter of fiscal 2025 compared with a net loss of \$23.0 million for the same period a year ago. Full year fiscal 2025 net loss was \$74.4 million compared to net loss of \$68.5 million for the fiscal year 2024.

## **About Ersodetug**

Ersodetug is a fully human monoclonal antibody that binds allosterically to the insulin receptor to decrease receptor over-activation by insulin and related substances (such as IGF-2) in the setting of hyperinsulinism (HI), thereby improving hypoglycemia. Because ersodetug acts downstream from the pancreas, it has the potential to be universally effective at treating hypoglycemia due to any congenital or acquired form of HI.

## **About Rezolute, Inc.**

Rezolute is a late-stage rare disease company focused on treating hypoglycemia caused by

hyperinsulinism (HI). The Company's antibody therapy, ersodetug, is designed to treat all forms of HI and has shown meaningful benefit in clinical trials and real-world use for the treatment of both congenital and tumor HI. For more information, visit [www.rezolutebio.com](http://www.rezolutebio.com).

## **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. These forward-looking statements include, but are not limited to the timing of the release of topline results from the sunRIZE trial, the applicability of ersodetug across multiple forms of hyperinsulinism, the timing of the release of topline results from the upLIFT study, the ability of ersodetug to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of ersodetug for the treatment of congenital hyperinsulinism, and statements regarding clinical trial timelines for ersodetug. 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 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.

## **Contacts:**

### **Rezolute, Inc.**

Christen Baglaneas

[cbaglaneas@rezolutebio.com](mailto:cbaglaneas@rezolutebio.com)

508-272-6717

### **Rezolute, Inc.**

#### **Condensed Consolidated Financial Statements Data**

**(in thousands, except per share data)**

	Three Months Ended		Year Ended	
	June 30,		June 30,	
	2025	2024	2025	2024
<b>Condensed Consolidated Statements of Operations Data:</b>				
Operating expenses:				
Research and development	\$ 20,863	\$ 19,089	\$ 61,527	\$ 55,743
General and administrative	4,987	4,013	18,367	14,680
Total operating expenses	25,850	23,102	79,894	70,423
Loss from operations	(25,850)	(23,102)	(79,894)	(70,423)
Non-operating income (expenses), net	1,460	126	5,482	1,964
Net loss	\$ (24,390)	\$ (22,976)	\$ (74,412)	\$ (68,459)

Basic and diluted net loss per common share	\$ (0.26)	\$ (0.44)	\$ (0.98)	\$ (1.33)
---	-----------	-----------	-----------	-----------

Shares used to compute basic and diluted net loss per common share	94,340	52,235	75,999	51,466
--	--------	--------	--------	--------

June 30, 2025	June 30, 2024
------------------	------------------

**Condensed Consolidated Balance Sheets Data:**

Cash and cash equivalents	\$ 94,107	\$ 70,396
Investments in marketable debt securities	73,751	56,741
Working capital	159,233	119,047
Total assets	175,490	132,737
Accumulated deficit	(403,856)	(329,444)
Total stockholders' equity	162,127	121,003



Source: Rezolute, Inc.