

February 12, 2025



Rezolute Reports Second Quarter Fiscal 2025 Financial Results and Provides Business Update

Ersodetug, a novel, fully human monoclonal antibody for the treatment of hyperinsulinism (HI), receives Breakthrough Therapy Designation and Orphan Drug Designation

Open-label arm (infant participants < 1 year old) of the sunRIZE study has been reviewed by a Data Monitoring Committee (DMC); target drug concentrations were safely reached at tested doses and infants are approved for enrollment into the double-blind portion of the study

REDWOOD CITY, Calif., Feb. 12, 2025 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a late-stage biopharmaceutical company dedicated to developing transformative therapies for rare diseases with serious unmet needs, today reported financial results and provided a business update for the three months ended December 31, 2024.

"We have made significant regulatory progress with ersodetug and our focus in 2025 remains squarely on advancing both Phase 3 trials for patients with congenital HI and tumor HI," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We are encouraged by our momentum and remain dedicated to providing meaningful and innovative treatments for patients with limited options."

Recent Pipeline Progress and Anticipated Milestones

Congenital HI

- The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation to ersodetug for the treatment of hypoglycemia due to congenital HI.
- sunRIZE, a Phase 3, multicenter, double-blind, randomized, controlled safety and efficacy registrational study, is ongoing.
 - Enrollment of U.S. participants is anticipated to occur in the second quarter of 2025.
 - Overall study enrollment expected to conclude in the second quarter of 2025, with topline results expected in the fourth quarter of 2025, subject to outcomes from an interim analysis.
- An independent Data Monitoring Committee (DMC) reviewed safety and pharmacokinetics of ersodetug in eight infant participants in the open-label arm of the sunRIZE study.
 - Ersodetug administered between 5-10 mg/kg during a bi-weekly loading phase and a monthly maintenance phase was generally safe and well-tolerated.
 - Observed ersodetug drug levels at peak and trough were comparable to

- exposures in older pediatric participants in the Phase 2b RIZE study and validate the chosen dose regimen of 5 and 10 mg/kg administered bi-weekly and monthly.
- Subsequent infant participants may be enrolled into the double-blind, placebo-controlled study.
 - The DMC did not analyze efficacy and the Company remains blinded to the results.
 - An interim analysis of the primary study endpoint (change in hypoglycemia events) is planned for this quarter, with results and study update to be announced early in the second quarter.
 - Three possible outcomes from the analysis include: (i) futility and the study should be stopped, (ii) continue the study as is or (iii) continue the study as is but increase the sample size by 33% (18 additional patients) to enhance statistical confidence in the final outcome.

Tumor HI

- During the quarter, FDA granted Orphan Drug Designation to ersodetug for the treatment of hypoglycemia due to tumor HI.
- A Phase 3 registrational study for ersodetug in patients with tumor HI is anticipated to begin in the first half of 2025.
- Topline results are expected in the second half of 2026.

Fiscal Second Quarter Financial Results

Cash, cash equivalents and investments in marketable securities were \$105.3 million as of December 31, 2024, compared to \$127.1 million as of June 30, 2024.

Research and development expenses were \$12.6 million for the second quarter of fiscal 2025, compared with \$12.0 million for the same period a year ago, with the increase primarily attributable to increased expenditures in clinical trial activities, manufacturing costs and higher personnel-related expenses, which include employee compensation.

General and administrative expenses were \$4.5 million for the second quarter of fiscal 2025, compared with \$3.2 million for the same period a year ago, with the increase primarily attributable to professional fees and employee-related expenses as a result of increased headcount.

Net loss was \$15.7 million for the second quarter of fiscal 2025 compared with a net loss of \$13.9 million for the same period a year ago.

About Ersodetug

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

About sunRIZE

The Phase 3 sunRIZE study is a multi-center, randomized, double-blind, placebo-controlled,

parallel arm study designed to evaluate the efficacy and safety of ersodetug in patients with congenital HI who are experiencing poorly controlled hypoglycemia. Participants between the ages of 3 months to 45 years old are eligible to participate. The study is enrolling up to 56 participants in more than a dozen countries around the world.

About Rezolute, Inc.

Rezolute is a late-stage rare disease company focused on significantly improving outcomes for individuals with hypoglycemia caused by hyperinsulinism (HI). The Company's antibody therapy, ersodetug, is designed to treat all forms of HI and has shown substantial benefit in clinical trials and real-world use for the treatment of congenital HI and tumor HI. For more information, visit 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 statements regarding the second quarter financial results of Rezolute, the efficacy of ersodetug in infant patient populations, the DMC approval and timeline of enrollment of infants into a double-blind and placebo-controlled study of ersodetug, the FDA's grant of the Breakthrough Therapy Designation for ersodetug, the Phase 3 sunRIZE study of ersodetug, 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. 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.

Contact:

Rezolute, Inc.
Christen Baglaneas

Rezolute, Inc.

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

	Three Months Ended		Six Months Ended	
	December 31,		December 31,	
	2024	2023	2024	2023
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	\$ 12,627	\$ 12,039	\$ 25,381	\$ 24,253
General and administrative	4,453	3,155	8,640	6,855
Total operating expenses	<u>17,080</u>	<u>15,194</u>	<u>34,021</u>	<u>31,108</u>
Loss from operations	(17,080)	(15,194)	(34,021)	(31,108)
Non-operating income, net	1,350	1,285	2,913	2,675
Net loss	<u>\$ (15,730)</u>	<u>\$ (13,909)</u>	<u>\$ (31,108)</u>	<u>\$ (28,433)</u>

Basic and diluted net loss per common share	<u>\$ (0.22)</u>	<u>\$ (0.27)</u>	<u>\$ (0.45)</u>	<u>\$ (0.55)</u>
---	------------------	------------------	------------------	------------------

Shares used to compute basic and diluted net loss per common share	<u>69,940</u>	<u>51,408</u>	<u>69,839</u>	<u>51,409</u>
--	---------------	---------------	---------------	---------------

December	June 30,
31,	2024
2024	2024

Condensed Consolidated Balance Sheets Data:

Cash and cash equivalents	\$ 8,932	\$ 70,396
Investments in marketable debt securities	96,383	56,741
Working capital	88,086	119,047
Total assets	112,007	132,737
Accumulated deficit	(360,552)	(329,444)
Total stockholders' equity	99,589	121,003



Source: Rezolute, Inc.