February 13, 2024

Rezolute Reports Second Quarter Fiscal 2024 Results and Provides Business Update

Phase 3 clinical study of RZ358 underway in patients with congenital hyperinsulinism (cHI); topline results expected in mid-2025

Benefit shown in individual patient cases with RZ358 for tumor-associated hyperinsulinism (taHI) under Expanded Access Program (EAP); drives alignment with FDA on unmet need and potential to move into late-stage clinical development to further evaluate RZ358 in this population

REDWOOD CITY, Calif., Feb. 13, 2024 (GLOBE NEWSWIRE) -- Rezolute, Inc. (Nasdaq: RZLT) ("Rezolute" or the "Company"), a clinical-stage biopharmaceutical company committed to developing novel, transformative therapies for serious metabolic and rare diseases, today announced its financial results for the second quarter of fiscal 2024 ended December 31, 2023, and provided an update on recent business developments and outlook.

"2024 is an exciting year of execution and milestones across our pipeline, with RZ358 continuing to demonstrate benefit to patients with hypoglycemia resulting from varying causes of hyperinsulinism, and in different indications," said Nevan Charles Elam, Chief Executive Officer and Founder of Rezolute. "We recently initiated sunRIZE, a global, pivotal, Phase 3 clinical study in patients with congenital hyperinsulinism, and we also continue to see favorable outcomes from our Expanded Access Program with RZ358, in patients with tumor-associated hyperinsulinism caused by insulinomas, for which we are evaluating a potential development program. Additionally, we completed enrollment in the Phase 2 study of RZ402 in patients with diabetic macular edema and look forward to reporting topline data from that program in the second quarter of 2024."

Clinical and Regulatory Highlights

RZ358 is a monoclonal antibody for the treatment of hyperinsulinism.

- cHI
  - Rezolute initiated sunRIZE, a global, pivotal, Phase 3 clinical study in participants with cHI, in Europe and other geographies outside of the U.S.
    - Topline results expected mid-2025.
  - Innovation and Licensing Application Passport (ILAP) designation awarded to RZ358 for the treatment of cHI by the U.K. Medicines and Healthcare products Regulatory Agency (MHRA).
    - Designation was granted based on the recognition of substantial unmet medical need in this condition and the potential benefit to patients as evidenced by the Phase 2b RIZE study results in cHI, which safely

demonstrated significant improvements in hypoglycemia.
        - Supplements analogous PRIME designation status already granted by the European Medicines Agency (EMA) in E.U.
- taHI
    - RZ358 has been shown to counteract excessive insulin action downstream, at the insulin-receptor on target organs. The unique mechanism of action of RZ358 makes the therapy a potential universal treatment for hypoglycemia resulting from any cause of hyperinsulinism, including neuroendocrine tumors (insulinomas).
    - Given the unmet need in taHI and the potential therapeutic benefit of RZ358 as demonstrated in the individual case reports from the EAP, the Company met with FDA in January 2024 (January Meeting) and received a favorable opinion from the Agency on the feasibility of RZ358 being studied in a late-stage clinical trial as a new development program and second rare disease indication for RZ358.
    - In the January Meeting, FDA indicated that current dose caps on cHI studies would not be applicable to taHI studies. Therefore, considering the indication is primarily adult, current partial clinical holds pertaining to cHI studies would be largely irrelevant in taHI.
    - The Company remains engaged with FDA in the attempt to resolve ongoing partial clinical holds on clinical studies in the cHI indication.

RZ402 is a selective and potent oral plasma kallikrein inhibitor for the treatment of diabetic macular edema (DME).

- Completed enrollment in Phase 2 U.S., multi-center, randomized, double-masked, placebo-controlled, parallel-arm study evaluating the safety, efficacy, and pharmacokinetics of RZ402 administered as an oral monotherapy over a 12-week treatment period in participants with DME who are naïve to or have received limited anti-VEGF injections.
- Topline results expected in the second quarter of 2024.

Corporate Highlights

- Expanded leadership team with appointment of Daron Evans, M.S., M.B.A, as Chief Financial Officer.
    - Mr. Evans has substantial experience leading public and private life science companies, with expertise in corporate finance, capital markets, and strategic transactions. He will help shepherd Rezolute through its next chapter in late-stage development.

Second Quarter Fiscal 2024 Financial Results

- Cash, cash equivalents and investments in marketable debt securities totaled $96.0 million as of December 31, 2023, compared to $118.4 million as of June 30, 2023

- Research and development expenses were $12.0 million for the second quarter of fiscal 2024, compared to $10.9 million for the same period in fiscal 2023, with the increase primarily attributable to increased expenditures in clinical trial activities and manufacturing costs

- General and administrative expenses were $3.2 million for the second quarter of fiscal 2024, compared to $3.4 million for the same period in fiscal 2023, with the decrease primarily attributable to lower personnel-related expenses

- Net loss was $13.9 million for the second quarter of fiscal 2024, compared to $13.6 million for the same period in fiscal 2023

About Rezolute, Inc.
Rezolute strives to disrupt current treatment paradigms by developing transformative therapies for devastating rare and chronic metabolic diseases. Its novel therapies hold the potential to both significantly improve outcomes and reduce the treatment burden for patients, treating physicians, and the healthcare system. Rezolute is steadfast in its mission to create profound, positive, and lasting impacts on patients' lives. Patient, clinician, and advocate voices are integrated in the Company's drug development process. Rezolute places an emphasis on understanding the patient's lived experiences, enabling the Company to boldly address a range of severe conditions. 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 appointment of Daron Evans as Chief Financial Officer, the sunRIZE Phase 3 clinical study, Phase 2 study of RZ402, the Expanded Access Program with RZ358, the ability of RZ358 to become an effective treatment for congenital hyperinsulinism, the effectiveness or future effectiveness of RZ358 for the treatment of congenital hyperinsulinism, and statements regarding clinical trial timelines for RZ358. 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.

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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,	
Condensed Consolidated Statements of Operations Data:	**2023**	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	$ 12,039	$ 10,945	$ 24,253	$ 18,649
General and administrative	3,155	3,447	6,855	5,961
Total operating expenses	15,194	14,392	31,108	24,610
Loss from operations	(15,194)	(14,392)	(31,108)	(24,610)
Non-operating income, net	1,285	836	2,675	1,223
Net loss	$ (13,909)	$ (13,556)	$ (28,433)	$ (23,387)
Basic and diluted net loss per common share	$ (0.27)	$ (0.26)	$ (0.55)	$ (0.46)
Shares used to compute basic and diluted net loss per common share	51,408	51,410	51,409	50,969

	December 31, 2023	June 30, 2023
Condensed Consolidated Balance Sheets Data:		

Cash and cash equivalents	$ 12,504	$ 16,036
Investments in marketable debt securities	83,446	102,330
Working capital	88,077	99,710
Total assets	102,150	123,721
Accumulated deficit	(289,418)	(260,985)
Total stockholders' equity	91,728	116,172

Source: Rezolute, Inc.