May 17, 2021

Rezolute Reports Third Quarter Fiscal 2021 Financial Results and Highlights Recent Company Progress

REDWOOD CITY, Calif., May 17, 2021 (GLOBE NEWSWIRE) -- **Rezolute, Inc.** (Nasdaq: RZLT), a clinical-stage biopharmaceutical company developing transformative therapies for metabolic diseases associated with chronic glucose imbalance, today announced its financial results for the fiscal third quarter ended March 31, 2021.

“We continue to advance the clinical development of our pipeline candidates, RZ358 and RZ402, with several milestones expected this year,” said Nevan Elam, Chief Executive Officer of Rezolute. “Highly encouraging topline results from our Phase 1 study of RZ402 support oral daily dosing for the treatment of diabetic macular edema, and we are on track to initiate a repeat-dose Phase 1b trial in the third quarter of 2021.”

Recent Business Highlights

- **Worldwide enrollment continues in the Phase 2b (RIZE) study of RZ358 for the treatment of patients with congenital hyperinsulinism (CHI) –** Enrollment is ongoing in the Phase 2b RIZE study of RZ358 for the treatment of CHI, with top line data expected in the second half of 2021. RZ358 is designed to increase glucose in the bloodstream of CHI patients by reducing insulin activity at its receptor.
- **Completed the Phase 1 study of RZ402 for the treatment of diabetic macular edema (DME) –** In May 2021, Rezolute announced topline results from its first-in-human Phase 1a clinical study of RZ402, the Company’s investigational oral plasma kallikrein inhibitor (PKI), for the treatment DME. Study results demonstrated the potential for once daily oral dosing and support the advancement of developmental activities toward Phase 2, including a Phase 1b multiple ascending dose study to be initiated in the third quarter of 2021.
- **Leading rare disease experts Appointed to the Board of Directors**– In March 2021, Rezolute announced the appointments of Wladimir Hogenhuis, M.D., MBA, and Nerissa C. Kreher, M.D., M.S., MBA to its Board of Directors.

Third Quarter Fiscal 2021 Financial Results

- Cash and cash equivalents totaled $32.0 million as of March 31, 2021.
- Research and development (R&D) expenses total $3.8 million in the third quarter of 2021 compared to $3.7 million in the same quarter of last year.
- General and administrative (G&A) expenses were $1.7 million in the third quarter of 2021 compared to $1.3 million in the prior period last year. The increase was primarily due to an increase in professional fees.
- Net loss was $3.7 million, or $0.44 per share, for the third quarter of fiscal 2021

compared to net loss of $5.0 million, or $0.86 per share, for the same period in fiscal 2020.

About Rezolute, Inc.
Rezolute is advancing transformative therapies for metabolic diseases associated with chronic glucose imbalance. The Company's lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (CHI), a rare pediatric endocrine disorder. The Company is also developing RZ402, an orally available plasma kallikrein inhibitor, for the treatment of 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 March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
	(unaudited)			
Condensed Consolidated Statements of Operations Data:				

Operating expenses:				
Research and development	3,758	3,733	10,598	12,005
General and administrative	1,725	1,337	5,660	4,964
Total operating expenses	5,483	5,070	16,258	16,969
Loss from operations	(5,483)	(5,070)	(16,258)	(16,969)
Non-operating income - interest and other	1,788	30	1,846	183
Net loss	$ (3,695)	$ (5,040)	$ (14,412)	$ (16,786)
Basic and diluted net loss per common share	$ (0.44)	$ (0.86)	$ (1.94)	$ (2.93)
Shares used to compute basic and diluted net loss per common share	8,352	5,866	7,445	5,719

	March 31, 2021	June 30, 2020
	(unaudited)	
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 31,989	$ 9,955
Working capital	28,607	7,292
Total assets	32,933	10,965
License fees payable to Xoma [(1)]	-	1,809
Accumulated deficit	(161,648)	(147,236)
Total stockholders' equity	29,132	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.

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Source: Rezolute, Inc.