September 15, 2021

Rezolute Reports Fourth Quarter and Full Year Fiscal 2021 Financial Results and Highlights Recent Company Progress

REDWOOD CITY, Calif., Sept. 15, 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 fourth quarter and fiscal full year ended June 30, 2021.

“We are very pleased with our overall progress, notably advancement of our clinical programs including RZ358 for congenital hyperinsulinism and RZ402 for diabetic macular edema,” said Nevan Elam, Chief Executive Officer and Founder of Rezolute. “We have continued to execute on the milestones we laid out prior to the COVID-19 pandemic, including the initiation of patient dosing in the second cohort of the Phase 2b trial of RZ358, and start of the Phase 1b multiple-ascending dose study of RZ402. In addition to these clinical accomplishments, we have further strengthened our leadership team and Scientific Advisory Board with key opinion leaders who will help us advance our programs.”

Recent Business Highlights

- **RZ358, monoclonal antibody for the treatment of congenital hyperinsulinism (HI) –** We are continuing to enroll patients into the second cohort of the Phase 2b RIZE study of RZ358 for the treatment of HI, with topline data expected in Q1 of 2022. RZ358 is designed to increase glucose in the bloodstream of HI patients by reducing insulin activity at its receptor.
- **RZ402, oral PKI for the treatment of diabetic macular edema (DME) –** In May 2021, we announced topline results from our first-in-human Phase 1a clinical study of RZ402, our investigational oral plasma kallikrein inhibitor (PKI), for the treatment of DME. Study results demonstrated the potential for once daily oral dosing. RZ402 is now in a Phase 1b multiple ascending dose study, with topline data expected in Q1 of 2022.
- **Key leadership appointments** – We announced the appointment of Davelyn Hood, MD, an expert in HI, as the Company’s Director, Scientific and Patient Affairs; and the appointment of Rajat Agrawal, MD, MS, a key opinion leader in ophthalmology, as Vice President, Clinical Development.
- **Scientific Advisory Board (SAB) expansion**– We announced the addition of two subject matter experts to our SAB: Quan Dong Nguyen, MD, MSc, FAAO, FARVO, Professor of Ophthalmology at the Byers Eye Institute, Stanford University School of Medicine and Dr. Adrian Vella, MD, Professor of Medicine in the Endocrinology Division at the Mayo Clinic College of Medicine.

Fourth Quarter and Full Year Fiscal 2021 Financial Results

- Cash and cash equivalents totaled $41.0 million as of June 30, 2021.
- Research and development (R&D) expenses were $4.4 million for the fourth quarter of fiscal 2021, compared to $2.4 million for the same period in fiscal 2020. Full fiscal year 2021 R&D expenses were $15.0 million, compared to $14.5 million in fiscal year 2020. The increases from fiscal year 2020 to fiscal year 2021 were primarily due to increased spending in compensation and benefits, licensing costs and clinical trial costs, partially offset by decreased spending in consulting, outside services and material manufacturing costs.
- General and administrative (G&A) expenses were $2.2 million for the fourth quarter of fiscal 2021, compared to $1.1 million for the same period in fiscal 2020. Full fiscal year 2021 G&A expenses were $7.9 million, compared to $6.1 million in fiscal year 2020. The increases from fiscal year 2020 to fiscal year 2021 were primarily due to compensation and benefits for our administrative and executive workforce along with increased spending in professional services.
- Net loss was $6.5 million, or $0.78 per share for the fourth quarter of fiscal 2021, compared to $3.5 million, or $0.60 per share for the same period in fiscal 2020. Full year fiscal 2021 net loss was $20.9 million, or $2.72 per share, compared to net loss of $20.3 million, or $3.54 per share, for the fiscal year 2020.

About Rezolute, Inc.
Rezolute is developing transformative therapies for metabolic diseases related to chronic glucose imbalance. The Company's lead clinical asset, RZ358, is in Phase 2b development for treatment of congenital hyperinsulinism (HI), 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 June 30,		Twelve Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
	(unaudited)			
Condensed Consolidated Statements of Operations Data:				
Operating expenses:				
Research and development	4,389	2,445	14,987	14,450
General and administrative	2,247	1,107	7,907	6,071
Total operating expenses	6,636	3,552	22,894	20,521
Loss from operations	(6,636)	(3,552)	(22,894)	(20,521)
Non-operating income (expense), net	146	5	1,992	188
Net loss	$(6,490)	$(3,547)	$ (20,902)	$ (20,333)
Basic and diluted net loss per common share	$ (0.78)	$ (0.60)	$ (2.72)	$ (3.54)
Shares used to compute basic and diluted net loss per common share	8,352	5,866	7,671	5,751

	June 30, 2021	June 30, 2020
Condensed Consolidated Balance Sheets Data:		
Cash and cash equivalents	$ 41,047	$ 9,955
Working capital	40,025	7,292
Total assets	42,609	10,965
Long term debt, net of discount (1)	13,968	-
License fees payable to Xoma (2)	-	1,809

Accumulated deficit	(168,138)	(147,236)
Total stockholders' equity	26,099	7,365

(1) In April 2021, we entered into a $30.0 million Loan Agreement with SLR and certain other Lenders. $15.0 million term A loan was funded on April 14, 2021.

(2) 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.

Source: Rezolute, Inc.