



Relay Therapeutics Reports First Quarter 2023 Financial Results and Corporate Highlights

May 04, 2023

Presented initial clinical data for RLY-2608 at American Association for Cancer Research (AACR) Annual Meeting 2023

Initiated clinical trial for RLY-5836, a chemically-distinct PI3K α pan-mutant inhibitor

\$937.8 million in cash, cash equivalents and investments at end of Q1 2023, expected to fund operations into 2025

CAMBRIDGE, Mass., May 04, 2023 (GLOBE NEWSWIRE) -- [Relay Therapeutics, Inc.](#) (Nasdaq: RLAY), a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies, today reported first quarter 2023 financial results and corporate highlights.

"We have made important progress so far in 2023 by continuing to advance our clinical and pre-clinical programs," said Sanjiv Patel, M.D., president and chief executive officer of Relay Therapeutics. "At the AACR Annual Meeting, we announced initial clinical data for RLY-2608, which showed that selectively inhibiting mutant PI3K α avoided key common off-target toxicities. Of the eight patients with measurable breast cancer who received a dose at target exposure, one experienced a confirmed partial response after data cut-off and the other seven experienced a best overall response of stable disease; seven of these patients continue on treatment. Given the early but promising nature of these data, we are moving quickly to initiate dose expansion cohorts in the second half of the year."

Recent Corporate Highlights

RLY-4008 (FGFR2 inhibitor)

- Presented data at AACR Annual Meeting 2023, which showed that food and esomeprazole did not have a clinically relevant effect on the pharmacokinetics (PK) of RLY-4008
- Full dose escalation data from the ReFocus trial accepted for presentation at 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, June 2-6, 2023

Breast Cancer Portfolio

- RLY-2608 (pan-mutant and isoform-selective PI3K α inhibitor)
 - Presented initial clinical data from the first-in-human ReDiscover trial at the [AACR Annual Meeting](#), which support initial clinical proof of mechanism, demonstrating that RLY-2608 achieved selective target engagement at multiple predicted efficacious doses with a favorable initial safety and tolerability profile. The cut-off date for these data was March 9, 2023. Key highlights include:
 - Multiple doses achieved sustained target exposure of approximately 80 percent or greater mutant PI3K α inhibition
 - No Grade 3 hyperglycemia, rash or diarrhea observed at target exposures
 - Favorable initial safety profile at target exposures with mostly low-grade adverse events that were manageable and reversible
 - Partial response in breast cancer patient with 12 prior lines of therapy, which was confirmed subsequent to the data cut-off date
 - Initial anti-tumor activity in breast cancer patients observed across a range of doses
 - Median treatment duration among the 27 patients with breast cancer was approximately 4 months, with 70 percent (19/27) still on treatment as of the cut-off date
 - Dose exploration is ongoing to determine the recommended dose(s) for the dose expansion cohorts, which Relay Therapeutics anticipates initiating in the second half of 2023
- RLY-5836 (pan-mutant and isoform-selective PI3K α inhibitor)
 - In April 2023, initiated a first-in-human trial in patients with advanced solid tumors with a PIK3CA (PI3K α) mutation
- RLY-2139 (CDK2 inhibitor)
 - Selected development candidate; anticipate early 2024 clinical start, pending regulatory authorization

Anticipated Upcoming Milestones

- RLY-4008
 - Full dose escalation data to be presented at ASCO Annual Meeting
 - Complete enrollment of pivotal cohort in the second half of 2023
 - Data from non-CCA expansion cohorts in the second half of 2023
- Breast Cancer
 - RLY-2608: initiation of expansion cohorts in the second half of 2023
 - ER α degrader: development candidate nomination in 2023
 - RLY-2139 (selective CDK2 inhibitor): clinical start in early 2024, pending regulatory authorization

First Quarter 2023 Financial Results

Cash, Cash Equivalents and Investments: As of March 31, 2023, cash, cash equivalents and investments totaled \$937.8 million compared to approximately \$1 billion as of December 31, 2022. Relay Therapeutics expects its current cash, cash equivalents and investments will be sufficient to fund its current operating plan into 2025.

R&D Expenses: Research and development expenses were \$82.8 million for the first quarter of 2023, as compared to \$51.7 million for the first quarter of 2022. The increase was primarily due to \$16.3 million of additional clinical trial expenses, \$9.4 million of additional employee-related costs, which include \$4.5 million of additional stock-based compensation expense, and \$3.3 million of additional costs for preclinical programs and platform technologies.

G&A Expenses: General and administrative expenses were \$19.6 million for the first quarter of 2023, as compared to \$16.1 million for the first quarter of 2022. The increase was primarily due to additional employee-related costs, which include \$3.6 million of additional stock-based compensation expense.

Net Loss: Net loss was \$94.2 million for the first quarter of 2023, or a net loss per share of \$0.78, as compared to a net loss of \$62.0 million for the first quarter of 2022, or a net loss per share of \$0.57.

About Relay Therapeutics

Relay Therapeutics (Nasdaq: RLAY) is a clinical-stage precision medicine company transforming the drug discovery process by combining leading-edge computational and experimental technologies with the goal of bringing life-changing therapies to patients. As the first of a new breed of biotech created at the intersection of complementary techniques and technologies, Relay Therapeutics aims to push the boundaries of what's possible in drug discovery. Its Dynamo™ platform integrates an array of leading-edge computational and experimental approaches designed to drug protein targets that have previously been intractable or inadequately addressed. Relay Therapeutics' initial focus is on enhancing small molecule therapeutic discovery in targeted oncology and genetic disease indications. For more information, please visit www.relaytx.com or [follow us on Twitter](#).

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Relay Therapeutics' strategy, business plans and focus; the progress and timing of the clinical development of the programs across Relay Therapeutics' portfolio, including the expected therapeutic benefits of its programs, timing of enrollment completion, potential efficacy and tolerability, and the timing and success of interactions with and approval of regulatory authorities; the timing of a clinical data update for RLY-4008, the initiation of expansion cohorts for RLY-2608, the clinical initiation of RLY-2139, and the nomination of a development candidate for Relay Therapeutics' ER α degrader program; expectations regarding Relay Therapeutics' pipeline, operating plan, use of capital, expenses and other financial results; and Relay Therapeutics' cash runway projection. The words "may," "might," "will," "could," "would," "should," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions, or the negative thereof, are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: the impact of global economic uncertainty, geopolitical instability, or public health epidemics or outbreaks of an infectious disease, such as COVID-19, on countries or regions in which Relay Therapeutics has operations or does business, as well as on the timing and anticipated results of its clinical trials, strategy, future operations and profitability; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary results of its preclinical or clinical trials may not be predictive of future or final results in connection with future clinical trials of its product candidates; Relay Therapeutics' ability to successfully demonstrate the safety and efficacy of its drug candidates; the timing and outcome of its planned interactions with regulatory authorities; and obtaining, maintaining and protecting its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Relay Therapeutics' most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as any subsequent filings with the Securities and Exchange Commission. In addition, any forward-looking statements represent Relay Therapeutics' views only as of today and should not be relied upon as representing its views as of any subsequent date. Relay Therapeutics explicitly disclaims any obligation to update any forward-looking statements. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Contact:

Megan Goulart
617-545-5526
mgoulart@relaytx.com

Media:

Dan Budwick

Relay Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue:		
License and other revenue	\$ 226	\$ 419
Total revenue	226	419
Operating expenses:		
Research and development expenses	\$ 82,827	\$ 51,667
Change in fair value of contingent consideration liability	(1,003)	(4,595)
General and administrative expenses	19,579	16,068
Total operating expenses	101,403	63,140
Loss from operations	(101,177)	(62,721)
Other income:		
Interest income	6,941	696
Other expense	(3)	(21)
Total other income, net	6,938	675
Net loss	\$ (94,239)	\$ (62,046)
Net loss per share, basic and diluted	\$ (0.78)	\$ (0.57)
Weighted average shares of common stock, basic and diluted	121,320,865	108,293,251
Other comprehensive loss:		
Unrealized holding gain (loss)	4,618	(8,130)
Total other comprehensive gain (loss)	4,618	(8,130)
Total comprehensive loss	\$ (89,621)	\$ (70,176)

Relay Therapeutics, Inc.
Selected Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	March 31,	December 31,
	2023	2022
Cash, cash equivalents and investments	\$ 937,804	\$ 998,917
Working capital (1)	887,921	955,796
Total assets	1,037,560	1,099,771
Total liabilities	154,148	149,553
Total stockholders' equity	883,412	950,218
Restricted cash	2,578	2,578

(1) Working capital is defined as current assets less current liabilities.

