Relay Therapeutics Reports Second Quarter 2023 Financial Results and Corporate Highlights

August 8, 2023

Initiated dose expansion cohort for RLY-2608 600mg BID + fulvestrant in patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer

Updated RLY-2608 600mg BID + fulvestrant data: interim clinical benefit rate of 86% (6 of 7 evaluable patients) & 1 of 5 patients with measurable disease achieved a partial response

Clinical benefit, including partial responses, observed across PI3Kα mutations and dose levels

Approximately $872 million in cash, cash equivalents and investments at end of Q2 2023, expected to fund operations into second half of 2025

CAMBRIDGE, Mass., Aug. 08, 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 second quarter 2023 financial results and corporate highlights.

“In the second quarter of 2023, we continued to advance our pipeline and progress our breast cancer portfolio,” said Sanjiv Patel, M.D., president and chief executive officer of Relay Therapeutics. “In July, we initiated the first RLY-2608 + fulvestrant dose expansion cohort. The additional RLY-2608 data supporting this decision, and the breadth of our breast cancer franchise, continue to drive our confidence that we are building a comprehensive solution for the more than 100,000 patients diagnosed with PI3Kα-mutated breast cancer in the U.S. each year.”

RLY-2608 Update

In July 2023, initiated dose expansion cohort with RLY-2608 600mg BID + fulvestrant in patients with PI3Kα-mutant, HR+, HER2– locally advanced or metastatic breast cancer

- Selection of 600mg BID dose supported by updated data from 17 breast cancer patients treated with RLY-2608 600mg BID + fulvestrant (cut-off date of July 24, 2023)
  - Interim clinical benefit rate (CBR) of 86 percent (6 of 7 CBR-evaluable patients) (CBR defined as the proportion of patients with stable disease, complete response, or partial response for at least 24 weeks)
  - Fifteen of 17 patients remain on treatment as of the cut-off date
  - One of five efficacy-evaluable patients with measurable disease achieved a confirmed partial response (PR) and remains on treatment as of the cut-off date (helical mutation)
  - Interim safety data compelling for use in metastatic breast cancer combinations
- Overall, updated data strengthen the RLY-2608 profile and continue to support selective target engagement across doses and mutation types with favorable interim safety and tolerability data. As of the July 24th data cut-off, 43 total breast cancer patients had received RLY-2608 monotherapy (n=4) or RLY-2608 + fulvestrant (n=39)
  - Four of 24 efficacy-evaluable patients with measurable disease achieved PRs, including three confirmed (400mg BID mono with double mutation; 100mg BID combo with kinase mutation; 600mg BID combo with helical mutation) and one unconfirmed (800mg BID combo with helical mutation)
  - The interim safety profile of RLY-2608 remains consistent with safety data previously reported at AACR
    - No adverse event-related discontinuations
    - No Grade 3+ hyperglycemia or diarrhea
- Data from ongoing dose escalation arms could support decision to bring an additional dose into dose expansion in the future
- Next data update expected in 2024

Additional Recent Corporate Highlights

RLY-4008

- Presented full dose escalation data from the ReFocus study at 2023 American Society of Clinical Oncology Annual Meeting

Anticipated Upcoming Milestones

- RLY-4008
  - Complete enrollment of pivotal cohort in the second half of 2023
  - Data from non-CCA expansion cohorts in the second half of 2023
- RLY-2608
  - Next data update expected in 2024
- ERα degrader: development candidate nomination in 2023
- RLY-2139 (selective CDK2 inhibitor): clinical start in early 2024, pending regulatory authorization

Second Quarter 2023 Financial Results

Cash, Cash Equivalents and Investments: As of June 30, 2023, cash, cash equivalents and investments totaled $871.6 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 the second half of 2025.

R&D Expenses: Research and development expenses were $88.2 million for the second quarter of 2023, as compared to $60.5 million for the second quarter of 2022. The increase was primarily due to $13.6 million of additional clinical trial expenses and $9.3 million of additional employee-related costs, which include $5.0 million of additional stock-based compensation expense.

G&A Expenses: General and administrative expenses were $20.1 million for the second quarter of 2023, as compared to $17.5 million for the second quarter of 2022. The increase was primarily due to additional employee-related costs, which include $3.3 million of additional stock-based compensation expense.

Net Loss: Net loss was $98.5 million for the second quarter of 2023, or a net loss per share of $0.81, as compared to a net loss of $76.8 million for the second quarter of 2022, or a net loss per share of $0.71.

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-2608, the initiation of an additional expansion cohort for RLY-2608, the timing of a clinical data update for RLY-4008, the completion of the pivotal cohort enrollment for RLY-4008, the clinical initiation of RLY-2139, and the nomination of a development candidate for Relay Therapeutics' ERα 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
License and other revenue	$ 119	$ 365	$ 345	$ 784
Total revenue	119	365	345	784
Operating expenses:				
Research and development expenses	$ 88,201	$ 60,511	$ 171,028	$ 112,178
Change in fair value of contingent consideration liability	(2,152)	200	(3,155)	(4,395)
General and administrative expenses	20,120	17,465	39,699	33,533
Total operating expenses	106,169	78,176	207,572	141,316
Loss from operations	(106,050)	(77,811)	(207,227)	(140,532)
Other income:				
Interest income	7,559	1,005	14,500	1,701
Other (expense) income	(14)	18	(17)	(3)
Total other income, net	7,545	1,023	14,483	1,698
Net loss	$ (98,505)	$ (76,788)	$ (192,744)	$ (138,834)
Net loss per share, basic and diluted	$ (0.81)	$ (0.71)	$ (1.59)	$ (1.28)
Weighted average shares of common stock, basic and diluted	121,680,844	108,644,329	121,501,849	108,469,760
Other comprehensive loss:				
Unrealized holding (loss) gain	(279)	(2,688)	4,339	(10,818)
Total other comprehensive (loss) gain	(279)	(2,688)	4,339	(10,818)
Total comprehensive loss	$ (98,784)	$ (79,476)	$ (188,405)	$ (149,652)

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

	June 30, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 871,573	$ 998,917
Working capital (1)	812,765	955,796
Total assets	962,016	1,099,771
Total liabilities	151,897	149,553
Total stockholders' equity	810,119	950,218
Restricted cash	2,707	2,578

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