Relay Therapeutics Reports Third Quarter 2024 Financial Results and Corporate Highlights

November 6, 2024

Reported interim RLY-2608 data demonstrating 9.2-month median PFS in heavily pre-treated patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer at RP2D

Plan to initiate 2L pivotal trial of RLY-2608 + fulvestrant in 2025

Approximately $840 million in cash, cash equivalents and investments at end of Q3 2024, expected to fund operations into second half of 2027

CAMBRIDGE, Mass., Nov. 06, 2024 (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 third quarter 2024 financial results and recent corporate highlights.

“In the third quarter, we reported very encouraging interim data showing that RLY-2608 + fulvestrant led to clinically meaningful progression free survival in heavily pre-treated patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer,” said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. “Based on these data, we are preparing to initiate a pivotal trial in 2L breast cancer in 2025, which we expect to be able to fully fund through top-line readout with our existing cash on hand. We also continue to progress our pre-clinical programs and look forward to bringing new programs into the clinic in 2025.”

Recent Corporate Highlights

RLY-2608 (ReDiscover study)

- RLY-2608 doublet:
  - Reported interim data for RLY-2608 + fulvestrant in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer who had previously received at least one prior CDK4/6 inhibitor. The data demonstrated clinically meaningful progression free survival (PFS) at the company’s recommended Phase 2 dose (RP2D) of 600mg BID. The cut-off date for these data was August 12, 2024. Key highlights included:
    - 9.2-month median PFS across all mutations & 10.3 months among patients with kinase mutations
    - 33% objective response rate (ORR) across all patients & 53% ORR in patients with kinase mutations at the RP2D
    - Favorable overall tolerability profile; at RP2D, only two patients discontinued treatment due to adverse events & only 1 patient experienced Grade 3 hyperglycemia
    - RLY-2608 + fulvestrant data will be presented at the San Antonio Breast Cancer Symposium, taking place December 10-13, 2024. Details of the poster spotlight presentation are as follows:
      - **Abstract Title**: PS7-01: Efficacy of RLY-2608, a mutant-selective PI3Kα inhibitor in patients with PIK3CA-mutant HR+HER2- advanced breast cancer: ReDiscover trial
      - **Abstract Number:** SESS-2211
      - **Session**: Concurrent Poster Spotlight Session 7: Targeting the ER and PI3K pathway: Novel drugs and combinations
      - **Date/Time**: Wednesday, December 11, 8:00-9:30 a.m. ET (7:00-8:30 a.m. CT)
  - Data support planned initiation of Phase 3 pivotal trial for RLY-2608 + fulvestrant in 2025
- RLY-2608 triplet: Continued to progress two potential front-line triplet regimens in patients with PI3Kα-mutated, HR+, HER2- metastatic breast cancer who had previously received at least one prior CDK4/6 inhibitor, including:
  - *CDK4/6*: RLY-2608 + ribociclib + fulvestrant dose escalation is currently testing biologically active doses of RLY-2608 and is on track to identify a dose of RLY-2608 that is combinable with full-dose ribociclib. Expansion cohorts are expected to initiate in the first half of 2025
  - *CDK4*: RLY-2608 + atirmociclib + fulvestrant trial on track to initiate by the end of 2024

Lirafugratinib (RLY-4008)

- Presented updated FGFR2 fusion tumor agnostic data at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, October 23-25, 2024
- Provided regulatory update regarding lirafugratinib regulatory path in which the FDA suggested that the company first file a new drug application (NDA) in cholangiocarcinoma, followed by a tumor agnostic supplemental NDA for FGFR2 fusions with data from more patients and more follow up
- Disclosed plans to seek a global commercialization partner for lirafugratinib in order to maintain company's focus on the remainder of the portfolio

Corporate Highlights

- Raised $230 million of gross proceeds in an underwritten follow-on public offering in September 2024
- Completed series of changes to streamline the research organization, collectively resulting in an expected $50 million in annual savings and workforce reduction of approximately 15%. Changes are part of the company's shift to becoming more development-focused in preparation for the upcoming RLY-2608 pivotal trial as well as new programs entering the clinic over the course of 2025

Anticipated Upcoming Milestones

- Breast Cancer
  - RLY-2608 + fulvestrant + ribociclib initial safety data in the fourth quarter of 2024
  - RLY-2608 + fulvestrant + atirmociclib clinical trial initiation by the end of 2024
  - RLY-2608 + fulvestrant + ribociclib dose expansion initiation in the first half of 2025
  - RLY-2608 + fulvestrant 2L Phase 3 trial initiation in 2025
- Pre-clinical
  - Vascular malformations: RLY-2608 clinical trial initiation in the first quarter of 2025
  - Fabry disease: clinical start in the second half of 2025
  - NRAS: clinical start in the second half of 2025

Third Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments: As of September 30, 2024, cash, cash equivalents and investments totaled $839.6 million compared to $750.1 million as of December 31, 2023. The company expects its current cash, cash equivalents and investments will be sufficient to fund its current operating plan into the second half of 2027.

Revenue: Revenue was $0 for the third quarter of 2024, as compared to $25.2 million for the third quarter of 2023. The decrease was primarily due to the recognition of previously received milestone payments under the company's Collaboration and License Agreement with Genentech, Inc. during the third quarter of 2023.

R&D Expenses: Research and development expenses were $76.6 million for the third quarter of 2024, as compared to $81.5 million for the third quarter of 2023. The decrease was primarily due to the impact of prioritization of certain programs in the company's pipeline, as previously disclosed in 2023 and earlier in 2024.

G&A Expenses: General and administrative expenses were $19.8 million for the third quarter of 2024, as compared to $18.5 million for the third quarter of 2023. The increase was primarily due to an increase in stock compensation expense, partially offset by decreases in other employee compensation costs and certain other general and administrative expenses.

Net Loss: Net loss was $88.1 million for the third quarter of 2024, or a net loss per share of $0.63, as compared to a net loss of $65.7 million for the third quarter of 2023, or a net loss per share of $0.54.

About Relay Therapeutics

Relay Therapeutics 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 and clinical initiation of the programs across Relay Therapeutics' portfolio; the progress toward bringing Relay Therapeutics' pre-clinical programs to the clinic, including anticipated timing; the expected therapeutic benefits and potential efficacy and tolerability of

RLY-2608, both as a monotherapy and in combination with other agents, and its other programs, including lirafugratinib; the timing and scope of clinical updates for RLY-2608; Relay Therapeutics' plan to seek a global commercialization partner for lirafugratinib; the interactions with regulatory authorities and any related approvals; the potential market opportunity for RLY-2608; the cash runway projection and the expectations regarding Relay Therapeutics' use of capital, expenses and potential cost savings. 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 and conflicts, or public health epidemics or outbreaks of an infectious disease 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 or pause of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary or interim 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 and that interim and early clinical data may change as more patient data become available and are subject to audit and verification procedures; 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
License and other revenue	$ —	$ 25,202	$ 10,007	$ 25,547
Total revenue	—	25,202	10,007	25,547
Operating expenses:				
Research and development expenses	$ 76,619	$ 81,494	$ 251,014	$ 252,522
Change in fair value of contingent consideration liability	—	(1,200)	(13,206)	(4,355)
General and administrative expenses	19,750	18,485	59,688	58,184
Total operating expenses	96,369	98,779	297,496	306,351
Loss from operations	(96,369)	(73,577)	(287,489)	(280,804)
Other income:				
Interest income	8,274	7,845	25,772	22,345
Other (expense) income	(10)	(2)	13	(19)
Total other income, net	8,264	7,843	25,785	22,326
Net loss	$ (88,105)	$ (65,734)	$ (261,704)	$ (258,478)
Net loss per share, basic and diluted	$ (0.63)	$ (0.54)	$ (1.94)	$ (2.12)
Weighted average shares of common stock, basic and diluted	140,229,056	122,231,255	134,651,728	121,843,116
Other comprehensive income (loss):				
Unrealized holding gain	3,849	2,695	2,705	7,034
Total other comprehensive income	3,849	2,695	2,705	7,034
Total comprehensive loss	$ (84,256)	$ (63,039)	$ (258,999)	$ (251,444)

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

	September 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 839,609	$ 750,086
Working capital (1)	818,161	739,834
Total assets	930,115	843,980
Total liabilities	91,254	91,977
Total stockholders' equity	838,861	752,003
Restricted cash	2,119	2,707

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