Relay Therapeutics Reports Fourth Quarter and Full Year 2024 Financial Results and Corporate Updates

Feb 26, 2025

Initiation of Phase 3 ReDiscover-2 trial of RLY-2608 + fulvestrant anticipated in the middle of 2025 in PI3Kα-mutated, CDK4/6 pre-treated, HR+/HER2- metastatic breast cancer

Presented interim data for RLY-2608 + fulvestrant showing 11.4-month median PFS in 2L patients with PI3Kα-mutated, HR+/HER2- metastatic breast cancer

Continued progression of other front-line breast cancer regimens, including initiation of atirmociclib triplet, and planning for development of future oral endocrine therapy combinations underway

Approximately $780 million in cash, cash equivalents and investments at end of Q4 2024, which will be prioritized to fully fund the execution of the ReDiscover-2 Phase 3 trial

CAMBRIDGE, Mass., Feb. 26, 2025 (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 fourth quarter and full year 2024 financial results and corporate highlights.

"Our RLY-2608 breast cancer program continued to advance and develop rapidly in 2024, driven by positive maturation of the RLY-2608 + fulvestrant doublet dataset, now with over 100 patients dosed and median PFS of 11.4 months in second-line patients. We also continue to make progress with our investigational triplet combinations, which we believe could potentially allow RLY-2608 to address patients in earlier settings," said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. "Looking forward into 2025, it is our top priority to continue advancing our clinical programs, including the initiation of the RLY-2608 + fulvestrant Phase 3 trial in breast cancer patients. With a strong capital position that supports the execution of that pivotal trial, and a team with proven development experience, I am confident in our abilities to meaningfully advance these programs towards patients in oncology and genetic disease areas."

Initiation of ReDiscover-2 Phase 3 trial of RLY-2608 + Fulvestrant in the Middle of 2025

- Relay Tx has conducted an end of Phase 2 meeting with the Food and Drug Administration (FDA) and announces the Phase 3 trial design, dose, and plans to initiate the trial in mid-2025
- Design
  - Planned Phase 3 registrational study (ReDiscover-2) is a randomized, open-label, multicenter clinical trial that will evaluate the safety and efficacy of RLY-2608 + fulvestrant in PI3Kα-mutated, HR+/HER2- advanced breast cancer patients previously treated with a CDK4/6 inhibitor
  - Comparator arm will be capivasertib + fulvestrant
  - Key inclusion criteria include:
    - Patients must be CDK4/6-experienced (either in the adjuvant or metastatic setting)
    - Patients must have been on frontline endocrine therapy containing regimen for >6 months
    - Patients may have seen up to 1 prior chemotherapy and no ADC in the metastatic setting
    - Metabolic inclusion criteria: HbA1c <7% and fasting plasma glucose <140 mg/dL at baseline
  - Target enrollment is 540 patients
  - The primary endpoint is progression free survival (PFS), per RECIST 1.1 criteria, tested hierarchically in patients with PI3Kα mutations in the kinase domain only and in patients with any PI3Kα mutation (kinase + non-kinase mutations)
  - Overall survival is a key secondary endpoint with overall response rate (ORR), duration of response and quality of life as additional secondary endpoints
- Dose
  - Phase 3 dose of RLY-2608 is 400mg twice daily (BID) in the fed state (fed)
  - A positive food effect has been observed when RLY-2608 was administered to patients in the fed state, which increased the exposure level of RLY-2608 compared to the fasted state (fasted)
  - The RLY-2608 400mg BID fed dose has been shown to achieve exposures equivalent to 600mg BID fasted in cancer patients
    - 600mg BID fasted was the dose used in our expansion cohorts

Additional Corporate Highlights

- RLY-2608:
  - RLY-2608 doublet: Presented interim clinical data from the open-label Phase 1b study for RLY-2608 + fulvestrant at the San Antonio Breast Cancer Symposium (SABCS) 2024, showing:
    - 11.4-month median PFS in second line (2L) patients with PI3Kα-mutated, HR+/HER2- locally advanced or metastatic breast cancer
    - 39% confirmed ORR across patients with measurable disease (n= 31)
    - 67% Clinical Benefit Rate (CBR) across all evaluable patients (32 of 48 CBR-evaluable patients; CBR defined as the proportion of patients with complete response, partial response or stable disease for at least 24 weeks)
    - Safety profile (n= 118) remained differentiated with mostly low-grade treatment- related adverse events
  - RLY-2608 triplet: Continued to advance 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:
    - Initiation of triplet cohort for RLY-2608 + fulvestrant + atirmociclib (Pfizer's selective CDK4 inhibitor) combination
    - Continued advancement of the ongoing RLY-2608 + fulvestrant + ribociclib combination cohort
  - Planning underway for development of next-generation endocrine therapy combinations with RLY-2608

- Lirafugratinib:
  - Entered exclusive global licensing agreement, granting Elevar Therapeutics worldwide rights to develop and commercialize lirafugratinib
- NRAS program:
  - Nominated development candidate, RLY-8161
- Research:
  - Continued to consolidate and focus the research platform and portfolio on a small number of high-value targets

Anticipated 2025 Milestones

- RLY-2608 in Breast Cancer:
  - Initiation of Phase 3 trial in the middle of 2025
  - Additional Phase 1b doublet data in 2025
- Vascular malformations: RLY-2608 clinical trial initiation in the first quarter of 2025
- NRAS and Fabry programs continue to advance towards IND and timing of clinical start for each program will be phased to optimize resources to ensure the execution of the ReDiscover-2 Phase 3 trial

Fourth Quarter and Full Year 2024 Financial Results

Cash, Cash Equivalents and Investments: As of December 31, 2024, cash, cash equivalents, and investments totaled $781.3 million compared to approximately $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: There was no revenue for the fourth quarters of 2024 and 2023. Revenue was $10.0 million for the full year 2024, as compared to $25.5 million for the full year 2023. The decrease was primarily due to the timing of milestones achieved, as well as revenue recognized thereon, under the company's Collaboration and License Agreement with Genentech, Inc.

R&D Expenses: Research and development expenses were $68.1 million for the fourth quarter of 2024, as compared to $77.5 million for the fourth quarter of 2023. Research and development expenses were $319.1 million for the full year 2024, as compared to $330.0 million for the full year 2023. The decreases were primarily due to the impact of prioritization of certain programs in the company's pipeline, as previously disclosed.

G&A Expenses: General and administrative expenses were $16.9 million for the fourth quarter of 2024, as compared to $16.8 million for the fourth quarter of 2023. General and administrative expenses were $76.6 million for the full year 2024, as compared to $75.0 million for the full year 2023.

Net Loss: Net loss was $76.0 million for the fourth quarter of 2024, or a net loss per share of $0.45, as compared to a net loss of $83.5 million for the fourth quarter of 2023, or a net loss per share of $0.67. Net loss was $337.7 million for the full year 2024, or a net loss per share of $2.36, as compared to a net loss of $342.0 million for the full year 2023, or a net loss per share of $2.79.

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 timing of data readout and other clinical and developmental milestones; 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, as well as the clinical data for RLY-2608; 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 and expenses. 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; significant political, trade, or regulatory developments beyond Relay Therapeutics' control; 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 December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
Revenue:				
License and other revenue	$ —	$ —	$ 10,007	$ 25,546
Total revenue	—	—	10,007	25,546
Operating expenses:				
Research and development expenses	$ 68,075	$ 77,496	$ 319,089	$ 330,018
Change in fair value of contingent consideration liability	—	(2,066)	(13,206)	(6,422)
General and administrative expenses	16,904	16,766	76,592	74,950
Total operating expenses	84,979	92,196	382,475	398,546
Loss from operations	(84,979)	(92,196)	(372,468)	(373,000)
Other income:				
Interest income	8,974	8,700	34,746	31,045
Other income (expense)	1	1	14	(18)
Total other income, net	8,975	8,701	34,760	31,027
Net loss	$ (76,004)	$ (83,495)	$ (337,708)	$ (341,973)
Net loss per share, basic and diluted	$ (0.45)	$ (0.67)	$ (2.36)	$ (2.79)
Weighted average shares of common stock, basic and diluted	167,337,579	124,752,843	142,867,844	122,576,527
Other comprehensive (loss) income:				
Unrealized holding loss (gain)	(3,500)	3,190	(795)	10,224
Total other comprehensive (loss) income	(3,500)	3,190	(795)	10,224
Total comprehensive loss	$ (79,504)	$ (80,305)	$ (338,503)	$ (331,749)

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

(Unaudited)

	December 31, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 781,323	$ 750,086
Working capital (1)	758,475	739,834
Total assets	871,296	843,980
Total liabilities	93,504	91,977
Total stockholders' equity	777,792	752,003
Restricted cash	2,119	2,707

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