Relay Therapeutics Reports Second Quarter 2024 Financial Results and Corporate Highlights

Aug 06, 2024

Announced 3 new programs, including genetic disease programs in vascular malformations, Fabry disease, as well as precision oncology program with NRAS-specific inhibitor

Initiated global clinical trial collaboration with Pfizer for combination development of RLY-2608 + fulvestrant + atirmociclib (CDK4i) in PI3Kα-mutated HR+/HER2- metastatic breast cancer, with clinical start planned by end of 2024

Approximately $688 million in cash, cash equivalents and investments at end of Q2 2024, expected to fund operations into second half of 2026

CAMBRIDGE, Mass., Aug. 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 second quarter 2024 financial results and corporate highlights.

“In the second quarter, we made important progress continuing to advance our clinical programs, which we believe has positioned us well for multiple data readouts later this year. Additionally, we look forward to expanding the RLY-2608 development program, with the initiation of a new triplet combination with Pfizer's novel investigative selective-CDK4 inhibitor atirmociclib by the end of the year,” said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. “Looking further ahead, we are very excited by the pre-clinical programs we unveiled in June, including our first two genetic disease programs, which will be important in driving our continued growth and diversification.”

Recent Corporate Highlights

RLY-2608 (ReDiscover study)

- RLY-2608 doublet: continued to enroll patients with PI3Kα-mutant, HR+, HER2- locally advanced or metastatic breast cancer in dose expansion cohorts of RLY-2608 400mg BID and 600mg BID in combination with fulvestrant
    - The next data update is expected in the fourth quarter of 2024 and will include approximately 100 patients across doses in the safety database and approximately 60 patients at the 600mg BID dose, including about 40 who have had the opportunity to be on RLY-2608 for at least 6 months
- RLY-2608 triplet:
    - *CDK4/6*: continued enrollment of RLY-2608 + fulvestrant + ribociclib triplet combination in patients with PI3Kα-mutant, HR+, HER2- locally advanced or metastatic breast cancer
    - *CDK4*: announced a clinical trial collaboration to evaluate atirmociclib, Pfizer’s investigative selective-CDK4 inhibitor, in combination with RLY-2608 and fulvestrant in patients with PI3Kα-mutant, HR+, HER2- metastatic breast cancer. The RLY-2608 + atirmociclib + fulvestrant triplet combination is planned to begin by the end of 2024
- RLY-2608 monotherapy: continued to enroll patients with unresectable or metastatic solid tumors with a PI3Kα mutation in dose escalation portion of RLY-2608 monotherapy arm and reported partial responses in multiple tumor types

Migoprotafib (GDC-1971)

- As previously disclosed, Genentech has terminated the collaboration agreement for the development and commercialization of migoprotafib
- The company will not continue development of migoprotafib

Pre-Clinical Programs

- Disclosed three new pre-clinical programs: vascular malformations, Fabry disease and NRAS
- Vascular Malformations
    - PI3Kα is the most common driver mutation among specific types of vascular malformations, which are a series of rare syndromes that occur due to atypical development of lymphatic and/or blood vessels and can become life-threatening, depending on what vessel(s) are involved
    - In the U.S., an estimated 170,000 people have one of the sub-types driven by a PI3Kα mutation, which include

PIK3CA-related overgrowth spectrum, lymphatic malformations, venous malformations and cerebral cavernous malformations

- A mutant selective PI3Kα inhibitor provides the opportunity for greater target coverage, leading to the potential for improved efficacy and better chronic tolerability
- Relay Therapeutics plans to initiate clinical development of RLY-2608 in vascular malformations in the first quarter of 2025

- Fabry Disease
  - In Fabry disease, harmful levels of Gb3 accumulate in blood cells and tissues throughout the body, due to insufficient αGal enzyme activity, which can lead to a range of symptoms, including potentially life-threatening ones such as kidney failure, heart failure and stroke. In the U.S., approximately 8,000 people have Fabry disease
  - Relay Therapeutics has created the first investigational non-inhibitory chaperone for Fabry disease, which is designed to stabilize the αGal protein without inhibiting its activity, thus enabling greater Gb3 clearance across organs
  - The company expects its non-inhibitory chaperone to enter the clinic in the second half of 2025
- NRAS
  - In the U.S., an estimated 28,000 people are diagnosed annually with mutated NRAS solid tumors, which are a known oncogene driver in the RAS family and can lead to a number of cancers, including melanoma, colorectal and non-small-cell lung
  - Relay Therapeutics has created the first NRAS-selective inhibitor, which has been designed to address the liabilities of current pan-RAS inhibitors by only binding to NRAS, while sparing KRAS and HRAS
  - The company expects to initiate clinical development of its NRAS-selective inhibitor in the second half of 2025

Anticipated Upcoming Milestones

- Breast Cancer
  - RLY-2608 + fulvestrant data update in the fourth quarter of 2024
  - 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 potential Phase 3 trial initiation in 2025
- Lirafugratinib: tumor agnostic data and regulatory update in the second half of 2024
- 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

Second Quarter 2024 Financial Results

Cash, Cash Equivalents and Investments: As of June 30, 2024, cash, cash equivalents and investments totaled $688.4 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 2026.

R&D Expenses: Research and development expenses were $92.0 million for the second quarter of 2024, as compared to $88.2 million for the second quarter of 2023. The increase was primarily due to additional external costs in connection with the ReDiscover trial for RLY-2608.

G&A Expenses: General and administrative expenses were $20.1 million for the second quarter of 2024, as well as for the second quarter of 2023.

Net Loss: Net loss was $92.2 million for the second quarter of 2024, or a net loss per share of $0.69, as compared to a net loss of $98.5 million for the second quarter of 2023, or a net loss per share of $0.81.

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, potential efficacy and tolerability, and the timing and success of interactions with and approval of regulatory authorities; the timing and progress of doublet and triplet combinations for RLY-2608, the timing and scope of clinical updates for RLY-2608, the timing of a clinical data and regulatory update for lirafugratinib; the timing of clinical initiation of Relay Therapeutics' various programs, including a potential pivotal trial for RLY-2608, clinical development in vascular malformations, clinical development of Relay Therapeutics' non-inhibitory chaperone, and clinical development of its NRAS-selective inhibitor; the potential of Relay Therapeutics' product candidates to address a major unmet medical need; the cash runway projection; the competitive landscape and potential market opportunities for Relay Therapeutics' product candidates; the expected strategic benefits under Relay Therapeutics' collaborations; and expectations regarding Relay Therapeutics' pipeline, operating plan, use of capital, expenses and other financial results. 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 results of its pre-clinical 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,	
	2024	2023	2024	2023
Revenue:				
License and other revenue	$ —	$ 119	$ 10,007	$ 345
Total revenue	—	119	10,007	345
Operating expenses:				
Research and development expenses	$ 91,992	$ 88,201	$ 174,395	$ 171,028
Change in fair value of contingent consideration liability	(11,374)	(2,152)	(13,206)	(3,155)
General and administrative expenses	20,139	20,120	39,938	39,699
Total operating expenses	100,757	106,169	201,127	207,572
Loss from operations	(100,757)	(106,050)	(191,120)	(207,227)
Other income:				
Interest income	8,547	7,559	17,498	14,500
Other (expense) income	(2)	(14)	23	(17)
Total other income, net	8,545	7,545	17,521	14,483
Net loss	$ (92,212)	$ (98,505)	$ (173,599)	$ (192,744)
Net loss per share, basic and diluted	$ (0.69)	$ (0.81)	$ (1.32)	$ (1.59)

Weighted average shares of common stock, basic and diluted	132,821,826	121,680,844	131,832,420	121,501,849
Other comprehensive (loss) income:				
Unrealized holding (loss) gain	(182)	(279)	(1,144)	4,339
Total other comprehensive (loss) income	(182)	(279)	(1,144)	4,339
Total comprehensive loss	$ (92,394)	$ (98,784)	$ (174,743)	$ (188,405)

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and investments	$ 688,415	$ 750,086
Working capital (1)	659,227	739,834
Total assets	772,750	843,980
Total liabilities	90,806	91,977
Total stockholders' equity	681,744	752,003
Restricted cash	2,707	2,707

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