



Relay Therapeutics Reports Third Quarter 2023 Financial Results and Corporate Highlights

Nov 02, 2023

Reported initial RLY-4008 (lirafugratinib) data demonstrating durable responses across multiple FGFR2-altered solid tumors

Announced plans to initiate RLY-2608 + fulvestrant + CDK4/6 triplet combinations in HR+/HER2- breast cancer by YE 2023

Updated pipeline to extend cash runway by approximately 1 year

Approximately \$811 million in cash, cash equivalents and investments at end of Q3 2023, expected to fund operations into second half of 2026

CAMBRIDGE, Mass., Nov. 02, 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 third quarter 2023 financial results and corporate highlights.

"We have made important progress expanding the number of patients we have the potential to help with our clinical programs," said Sanjiv Patel, M.D., President and Chief Executive Officer of Relay Therapeutics. "We presented data at the Triple Meeting demonstrating the potential of lirafugratinib in patients with many types of FGFR2-altered tumors, and we are working to initiate RLY-2608 triplet combinations this year with the goal of being able to treat patients with earlier stage breast cancer. We have focused our clinical development and execution to extend our cash runway into the second half of 2026 with the goal of having the resources to execute these programs, and we are continuing to advance them as quickly as possible."

Recent Corporate Highlights

RLY-4008 (lirafugratinib)

- Presented initial clinical data in patients with FGFR2-altered solid tumors at the [2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics](#), which demonstrated activity across several sub-groups, including in patients with FGFR2-fusion tumors and in patients with FGFR2-altered HR+/HER2- breast cancer. The cut-off date for these data was August 23, 2023. Key highlights include:
 - FGFR2 fusions: Nine of 26 patients experienced a confirmed partial response (PR) (35% overall response rate (ORR)), with 63 percent of responders experiencing a duration of response of at least 6 months
 - HR+/HER2- breast cancer, all FGFR2 alterations: Four of 10 patients achieved PRs (40% ORR), with all responders having a duration of response of at least 6 months, and the longest duration of response 72 weeks and ongoing as of the data cut-off
 - Patients were very heavily pre-treated (median of 6 prior lines of therapy) with prior targeted therapies (100%), prior chemotherapy/ADC (93%), prior endocrine therapy (79%) and prior CDK4/6 (71%)
 - FGFR2 amplifications: Eight of 34 patients experienced a PR (24% ORR), with 43 percent of responders experiencing a duration of response of at least 6 months
- Completed enrollment in the pivotal expansion cohort in patients with FGFR2-fusion cholangiocarcinoma (CCA) who have not previously received an FGFR inhibitor
- Paused near-term commercial readiness activities for CCA to align with the broader tumor agnostic opportunity being pursued

RLY-2608

- Announced plans to initiate RLY-2608 + fulvestrant + CDK4/6 triplet combinations in patients with PI3K α -mutant, HR+, HER2- locally advanced or metastatic breast cancer by the end of 2023

Pre-Clinical

- Paused further development efforts on RLY-2139 (CDK2 inhibitor)

Anticipated Upcoming Milestones

- Lirafugratinib: report additional tumor agnostic clinical data and regulatory update in 2024
- PI3K α : next data update expected in 2024

- Pre-clinical: disclose new program(s) in 2024

Third Quarter 2023 Financial Results

Cash, Cash Equivalents and Investments: As of September 30, 2023, cash, cash equivalents and investments totaled \$810.6 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 2026.

Revenue: Revenue was \$25.2 million for the third quarter of 2023, as compared to \$0.3 million for the third quarter of 2022. The increase was primarily due to the recognition of previously received milestone payments under the company's Collaboration and License Agreement with Genentech, Inc.

R&D Expenses: Research and development expenses were \$81.5 million for the third quarter of 2023, as compared to \$66.9 million for the third quarter of 2022. The increase was primarily due to \$8.2 million of additional clinical trial expenses and \$7.4 million of additional employee-related costs, which include \$4.5 million of additional stock compensation expense.

G&A Expenses: General and administrative expenses were \$18.5 million for the third quarter of 2023, as compared to \$16.1 million for the third quarter of 2022. The increase was primarily due to additional stock compensation expense.

Net Loss: Net loss was \$65.7 million for the third quarter of 2023, or a net loss per share of \$0.54, as compared to a net loss of \$84.2 million for the third quarter of 2022, or a net loss per share of \$0.76.

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 of a clinical data update for the PI3Ka franchise, the initiation of triplet combinations for RLY-2608, the timing of a clinical data and regulatory update for lirafugratinib, and the timing of disclosure of additional pre-clinical programs; 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 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
License and other revenue	\$ 25,202	\$ 344	\$ 25,547	\$ 1,128
Total revenue	25,202	344	25,547	1,128
Operating expenses:				
Research and development expenses	\$ 81,494	\$ 66,900	\$ 252,522	\$ 179,078
Change in fair value of contingent consideration liability	(1,200)	3,262	(4,355)	(1,133)
General and administrative expenses	18,485	16,074	58,184	49,607
Total operating expenses	98,779	86,236	306,351	227,552
Loss from operations	(73,577)	(85,892)	(280,804)	(226,424)
Other income:				
Interest income	7,845	1,713	22,345	3,414
Other (expense) income	(2)	7	(19)	4
Total other income, net	7,843	1,720	22,326	3,418
Net loss	\$ (65,734)	\$ (84,172)	\$ (258,478)	\$ (223,006)
Net loss per share, basic and diluted	\$ (0.54)	\$ (0.76)	\$ (2.12)	\$ (2.04)
Weighted average shares of common stock, basic and diluted	122,231,255	110,905,940	121,843,116	109,290,743
Other comprehensive loss:				
Unrealized holding gain (loss)	2,695	(1,483)	7,034	(12,301)
Total other comprehensive gain (loss)	2,695	(1,483)	7,034	(12,301)
Total comprehensive loss	\$ (63,039)	\$ (85,655)	\$ (251,444)	\$ (235,307)

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

	September 30, 2023	December 31, 2022
Cash, cash equivalents and investments	\$ 810,615	\$ 998,917
Working capital (1)	781,050	955,796
Total assets	906,959	1,099,771
Total liabilities	128,586	149,553
Total stockholders' equity	778,373	950,218
Restricted cash	2,707	2,578

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



Source: Relay Therapeutics, Inc.