



Relay Therapeutics Reports Third Quarter 2022 Financial Results and Corporate Highlights

Nov 03, 2022

Shared 88% overall response rate (ORR) from interim data of RLY-4008 in pan-FGFR treatment (FGFRi)-naïve

FGFR2-fusion cholangiocarcinoma (CCA) patients treated at the pivotal dose at European Society for Medical Oncology (ESMO) Congress

\$1.1 billion in cash, cash equivalents and investments at the end of third quarter 2022

CAMBRIDGE, Mass., Nov. 03, 2022 (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 2022 financial results and recent corporate highlights.

"We continue to deliver on our execution focus for 2022 and the third quarter uniquely exemplified this," said Sanjiv Patel, M.D., Relay Therapeutics' president and chief executive officer. "We presented interim data at the ESMO Congress that demonstrate an 88% overall response rate at the pivotal dose of RLY-4008 and further support our hypothesis that selective inhibition of FGFR2 can improve the treatment for patients with FGFR2-driven tumors. The interim data demonstrate the potential power of our Dynamo platform to build transformative therapies for patients. We continue to build momentum upon our achievements this year and we believe we have the team, platform and capital to deliver upon numerous milestones."

Recent Corporate Highlights

- Continued to enroll patients across both dose escalation cohorts of the first-in-human trial for RLY-2608, a pan-mutant and isoform-selective PI3K α inhibitor, assessing it as a single agent for patients with unresectable or metastatic solid tumors with PI3K α mutation and evaluating RLY-2608 in combination with fulvestrant for patients with HR+, HER2-, PI3K α -mutated, locally advanced or metastatic breast cancer.
- Presented updated RLY-4008 data as of the August 1, 2022 cut-off date at ESMO Congress 2022, including key highlights:
 - 15 out of 17 of the FGFRi-naïve FGFR2-fusion CCA efficacy evaluable patients at the pivotal dose experienced a partial response resulting in an 88% interim ORR (14 confirmed, 1 unconfirmed in an ongoing patient).
 - 13 out of these 15 responders remain on treatment; 1 responder came off study to be resected with curative intent.
 - More broadly across all dose levels and schedules, 38 FGFRi-naïve FGFR2-fusion CCA patients were eligible for efficacy evaluation, of which 24 experienced a partial response resulting in a 63% interim ORR (22 confirmed, 2 unconfirmed).
 - Most treatment emergent adverse events were expected FGFR2 on-target, low-grade, monitorable, manageable and largely reversible.
 - There were no observed Grade 4 or 5 adverse events, and off-target toxicities of hyperphosphatemia and diarrhea continued to be clinically insignificant.
- Raised \$300 million of gross proceeds in an underwritten follow-on public offering.

Third Quarter 2022 Financial Results

Cash, Cash Equivalents and Investments: As of September 30, 2022, cash, cash equivalents and investments totaled approximately \$1.1 billion compared to \$958 million as of December 31, 2021. Relay Therapeutics expects its current cash, cash equivalents and investments will be sufficient to fund its current operating plan into 2025.

R&D Expenses: Research and development expenses were \$66.9 million for the third quarter of 2022, as compared to \$45.0 million for the third quarter of 2021. The increase was primarily due to \$11.9 million related to clinical trial expenses, \$5.6 million of additional employee related costs, which includes \$1.7 million in stock-based compensation, and \$2.7 million related to preclinical programs and platform technologies.

G&A Expenses: General and administrative expenses were \$16.1 million for third quarter of 2022, as compared to \$14.7 million for the third quarter of 2021. The increase was primarily due to additional employee related costs.

Net Loss: Net loss was \$84.2 million for the third quarter of 2022, or a net loss per share of \$0.76, as compared to a net loss of \$60.8 million for the third quarter of 2021, or a net loss per share of \$0.66.

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 disparate 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. 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 updates on the clinical development of the programs across Relay Therapeutics' portfolio, including the expected therapeutic benefits of its programs, including potential efficacy and tolerability; whether preliminary results from Relay Therapeutics' preclinical or clinical trials will be predictive of the final results of the trials or any future clinical trials of its product candidates; the possibility that unconfirmed results from these trials will not be confirmed by additional data as the clinical trials progress; Relay Therapeutics' expectations with respect to its potential pivotal dose for RLY-4008, including potential regulatory filings and interactions; expectations regarding Relay Therapeutics' operating plan, use of capital, expenses and other financial results during 2022 and in the future; 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 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 the ongoing COVID-19 pandemic 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 and future operations; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the results of its clinical trials may not be predictive of future results in connection with future clinical trials; 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.

Contact:

Caroline Glen
617-370-8837
cglen@relaytx.com

Media:

Dan Budwick
1AB
973-271-6085
dan@1abmedia.com

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,	
	2022	2021	2022	2021
Revenue:				
License and other revenue	\$ 344	\$ 666	\$ 1,128	\$ 2,462
Total revenue	344	666	1,128	2,462
Operating expenses:				
Research and development expenses	\$ 66,900	\$ 44,974	\$ 179,078	\$ 120,743
In-process research and development expenses	—	—	—	123,000
Loss on initial consolidation of variable interest entity	—	—	—	11,855
Change in fair value of contingent consideration liability	3,262	2,000	(1,133)	2,000
General and administrative expenses	16,074	14,682	49,607	41,839
Total operating expenses	86,236	61,656	227,552	299,437
Loss from operations	(85,892)	(60,990)	(226,424)	(296,975)
Other income:				
Interest income	1,713	157	3,414	563
Other income (expense)	7	—	4	(4)
Total other income, net	1,720	157	3,418	559
Net loss	\$ (84,172)	\$ (60,833)	\$ (223,006)	\$ (296,416)

Net loss per share, basic and diluted	\$	0.76	\$	0.66	\$	2.04	\$	3.20
Weighted average shares of common stock, basic and diluted		110,905,940		92,692,515		109,290,743		92,599,781
Other comprehensive (loss) income:								
Unrealized holding (loss) gain		(1,483)		74		(12,301)		(54)
Total other comprehensive (loss) income		(1,483)		74		(12,301)		(54)
Total comprehensive loss	\$	(85,655)	\$	(60,759)	\$	(235,307)	\$	(296,470)

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

	September 30, 2022	December 31, 2021
Cash, cash equivalents and investments	\$ 1,053,792	\$ 958,073
Working capital (1)	1,015,870	951,921
Total assets	1,168,718	1,008,443
Total liabilities	168,949	110,635
Total stockholders' equity	999,769	897,808
Restricted cash	2,578	2,578

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