Relay Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Corporate Highlights

Feb 23, 2023

Advanced RLY-4008: Reported interim data with 88% overall response rate at pivotal dose and 63% across all doses in pan-FGFR treatment-naïve, FGFR2-fusion cholangiocarcinoma patients & announced anticipated registrational path

Progressed & expanded breast cancer portfolio: Continued monotherapy and initiated combination arms in study of PI3Kα inhibitor RLY-2608 & disclosed 3 new pre-clinical programs

Raised $300.0 million of gross proceeds in underwritten follow-on public offering

Approximately $1 billion in cash, cash equivalents and investments at end of 2022, expected to fund operations into 2025

CAMBRIDGE, Mass., Feb. 23, 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 fourth quarter and full year 2022 financial results and corporate highlights.

“We successfully executed against our strategy in 2022, advancing multiple clinical and pre-clinical programs and continuing to demonstrate the power of our Dynamo platform,” said Sanjiv Patel, M.D., president and chief executive officer of Relay Therapeutics. “We reported additional RLY-4008 interim data showing an overall response rate of 63% across all doses and 88% at the pivotal dose, building on the previously reported early data and supporting our belief that limiting off-target effects and toxicity can allow us to improve efficacy. We also expanded our breast cancer portfolio, continuing clinical development of RLY-2608 and announcing three new programs. With a robust pipeline and cash in hand to fund us into 2025, we are excited to continue to execute on our plans and deliver against our milestones this year, as we work toward our goal of bringing life-changing therapies to patients.”

2022 Corporate Highlights

RLY-4008 (FGFR2 inhibitor)

- Presented additional interim data from patients with FGFRi-naïve FGFR2-fusion cholangiocarcinoma (CCA) at European Society for Medical Oncology (ESMO) Congress 2022. Key highlights included:
    - All doses – 63% interim overall response rate (ORR): across all dose levels and schedules, 24 of 38 efficacy-evaluable patients experienced a partial response (22 confirmed, 2 unconfirmed)
    - Pivotal dose (70 mg once daily) – 88% ORR: 15 of 17 efficacy-evaluable patients experienced a partial response (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
    - 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
- Based on discussions with the U.S. Food and Drug Administration, moved forward with a single-arm pivotal trial design for patients with pan-FGFR (FGFRi) treatment-naïve FGFR2-fusion CCA at 70 mg once daily to potentially support accelerated approval
    - Anticipate completing enrollment in pivotal cohort in the second half of 2023

Breast Cancer Portfolio

- RLY-2608 (pan-mutant and isoform-selective PI3Kα inhibitor)
    - Monotherapy: Following December 2021 initiation of the first-in-human trial, continued to enroll dose escalation portion of trial assessing RLY-2608 as a single agent in patients with unresectable or metastatic solid tumors with PI3Kα mutation
    - Combination: In April 2022, initiated dose escalation portion of a fulvestrant combination arm in patients with HR+, HER2–, PI3Kα-mutated, locally advanced or metastatic breast cancer
    - Anticipate disclosing initial clinical data from both dose escalation portions in the first half of 2023
- In June 2022, disclosed three new programs:

- Selective CDK2 inhibitor, anticipated clinical start in early 2024
- ERα degrader, development candidate nomination in 2023
- RLY-5836 (chemically distinct pan mutant-PI3Kα inhibitor), expected to enter the clinic in the second quarter of 2023

Corporate Highlights

- Appointed Sekar Kathiresan, M.D., CEO of Verve Therapeutics, to Board of Directors
- Raised $300.0 million of gross proceeds in an underwritten follow-on public offering

2023 Anticipated Milestones

- RLY-4008
  - Full dose escalation data in the first half of 2023
  - Complete enrollment of pivotal cohort in the second half of 2023
  - Data from non-CCA expansion cohorts in the second half of 2023
- Breast Cancer
  - RLY-2608: initial clinical data from dose escalation portions of monotherapy and combination arms of trial in the first half of 2023
  - RLY-5836: clinical start in the second quarter of 2023
  - ERα degrader: development candidate nomination in 2023
  - Selective CDK2 inhibitor: clinical start in early 2024

Fourth Quarter and Full Year 2022 Financial Results

Cash, Cash Equivalents and Investments: As of December 31, 2022, cash, cash equivalents and investments totaled approximately $1 billion compared to $958.1 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 $67.3 million for the fourth quarter of 2022, as compared to $51.9 million for the fourth quarter of 2021. The increase was primarily due to $6.8 million of additional clinical trial expenses and $6.3 million of additional employee related costs, which includes $3.1 million of additional stock-based compensation expense. Research and development expenses were $246.4 million for the full year 2022, as compared to $172.7 million for the full year 2021. The increase was primarily due to $32.7 million of additional clinical trial expenses, $24.7 million of additional employee related costs, which includes $5.7 million of additional stock-based compensation expense, and $10.8 million of additional preclinical programs and platform technologies.

G&A Expenses: General and administrative expenses were $16.4 million for the fourth quarter of 2022, as compared to $15.5 million for the fourth quarter of 2021. The increase was primarily due to additional employee related costs, which includes $0.5 million of additional stock-based compensation expense. General and administrative expenses were $66.0 million for the full year 2022, as compared to $57.4 million for the full year 2021. The increase was primarily due to additional employee related costs, which includes $1.9 million of additional stock-based compensation expense.

Net Loss: Net loss was $67.5 million for the fourth quarter of 2022, or a net loss per share of $0.56, as compared to a net loss of $67.5 million for the fourth quarter of 2021, or a net loss per share of $0.64. Net loss was $290.5 million for the full year 2022, or a net loss per share of $2.59, as compared to a net loss of $363.9 million for the full year 2021, or a net loss per share of $3.82. Net loss for the full year 2021 included one-time expenses of $134.9 million associated with the acquisition of ZebiAI Therapeutics, Inc.

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, timing of enrollment completion, and potential efficacy and tolerability; the timing of a clinical data update for RLY-4008 and RLY-2608, the clinical initiation of RLY-5836 and Relay Therapeutics' selective CDK2 inhibitor, and the nomination of a development candidate for Relay Therapeutics' ERα degrader program; 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' pipeline, 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, 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, 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, future operations and profitability; the delay of any current or planned clinical trials or the development of Relay Therapeutics' drug candidates; the risk that the preliminary 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; 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.
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,	
	2022	**2021**	**2022**	**2021**
Revenue:				
License and other revenue	$ 253	$ 567	$ 1,381	$ 3,029
Total revenue	253	567	1,381	3,029
Operating expenses:				
Research and development expenses	$ 67,277	$ 51,907	$ 246,355	$ 172,650
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	(10,544)	836	(11,677)	2,836
General and administrative expenses	16,371	15,547	65,978	57,386
Total operating expenses	73,104	68,290	300,656	367,727
Loss from operations	(72,851)	(67,723)	(299,275)	(364,698)
Other income:				
Interest income	5,372	267	8,786	830
Other (expense) income	(24)	—	(20)	(4)
Total other income, net	5,348	267	8,766	826
Net loss	$ (67,503)	$ (67,456)	$ (290,509)	$ (363,872)
Net loss per share, basic and diluted	$ 0.56	$ 0.64	$ 2.59	$ 3.82
Weighted average shares of common stock, basic and diluted	120,966,401	105,584,819	112,233,649	95,136,719
Other comprehensive income (loss):				
Unrealized holding gain (loss)	2,969	(1,098)	(9,332)	(1,152)
Total other comprehensive (loss) income	2,969	(1,098)	(9,332)	(1,152)
Total comprehensive loss	$ (64,534)	$ (68,554)	$ (299,841)	$ (365,024)

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and investments	$ 998,917	$ 958,073
Working capital (1)	955,796	951,921

Total assets	1,099,771	1,008,443
Total liabilities	149,553	110,635
Total stockholders’ equity	950,218	897,808
Restricted cash	2,578	2,578

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