Repare Therapeutics Announces Portfolio Re-Prioritization, Partnering Initiatives and Cost Reductions

January 9, 2025

Realigning resources to extend runway to mid-2027

Focus on clinical development of RP-1664 (PLK4 inhibitor) and RP-3467 (Polθ ATPase inhibitor), with initial clinical readouts expected beginning in Q3 2025

Exploring partnerships for continued development of Lunre+Camo and other assets

CAMBRIDGE, Mass. & MONTREAL--(BUSINESS WIRE)--Jan. 9, 2025-- Repare Therapeutics Inc. (“Repare” or the “Company”) (Nasdaq: RPTX), a leading clinical-stage precision oncology company, today announced a re-alignment of resources and a re-prioritization of its clinical portfolio to focus on the continued advancement of its Phase 1 clinical programs, RP-1664 (PLK4 inhibitor) and RP-3467 (Polθ ATPase inhibitor). Repare also announced its intention to seek partnering opportunities across its portfolio, including for lunresertib and camonsertib (“Lunre+Camo”) prior to any start of pivotal development. The consequent savings of late-stage clinical funding combined with planned cost and headcount reductions are expected to extend Repare’s cash runway into mid-2027.

“While Lunre+Camo demonstrated positive results from our Phase 1 clinical trial, after careful consideration we have decided to progress this program into pivotal trials contingent on securing a strategic partner to fund further development. We are focused on achieving near-term inflection points for our Phase 1 clinical assets, RP-1664 and RP-3467, both of which have the potential to address significant unmet patient needs and deliver important catalysts in 2025,” said Lloyd M. Segal, President and Chief Executive Officer of Repare. “Combined with other initiatives, these changes, which we will implement later this quarter, provide the foundation for meaningful value creation.”

Recent Pipeline Progress & Upcoming Milestones of Prioritized Clinical Programs:

RP-1664: First-in-class, highly selective, oral inhibitor of PLK4

Repare is evaluating RP-1664 as a monotherapy in the Phase 1 LIONS clinical trial in adult and adolescent patients with TRIM37-high solid tumors.

Upcoming Expected Milestones:

- Q3 2025: Initiation of a Phase 1/2 expansion trial in pediatric neuroblastoma
- Q4 2025: Initial topline safety, tolerability and early efficacy data from the LIONS trial
- Mid-2026: Trial completion, final trial readout for proof-of-concept from the LIONS trial

RP-3467: Potential best-in-class Polθ ATPase inhibitor

Repare is dosing patients in the Phase 1 POLAR clinical trial evaluating RP-3467 alone and in combination with the poly-ADP ribose polymerase (PARP) inhibitor, olaparib. This trial is enrolling patients with locally advanced or metastatic epithelial ovarian cancer, metastatic breast cancer, metastatic castration-resistant prostate cancer, or pancreatic adenocarcinoma.

Upcoming Expected Milestones:

- Q3 2025: Topline safety, tolerability and early efficacy data from the POLAR trial in monotherapy and in combination with olaparib.

Lunresertib and Camonsertib

Repare recently reported positive efficacy and safety data from the Phase 1 MYTHIC gynecologic expansion clinical trial evaluating the combination of lunresertib and camonsertib (Lunre+Camo) at the recommended Phase 2 dose (RP2D) in patients with endometrial cancer (EC) and platinum-resistant ovarian cancer (PROC). Nearly half of patients with gynecologic cancers maintained progression-free survival (PFS) at 24 weeks, comparing favorably to PFS for current standard of care. Repare intends to seek partnering opportunities for this program as a condition to advancing the program into planned and regulatory-supported pivotal development.

Repare is currently evaluating lunresertib in combination with Debio 0123, a highly selective, brain-penetrant, clinical WEE1 inhibitor, in patients with advanced solid tumors harboring *CCNE1* amplification or *FBXW7* or *PPP2R1A* deleterious alterations as part of an ongoing 50/50 cost sharing collaboration with Debiopharm.

The Company will not continue to develop lunresertib or camonsertib in other studies, including the ongoing camonsertib non-small cell lung cancer expansion study, absent securing a partnership with a development partner.

Upcoming Expected Milestone:

- Q2 2025: Enrollment completion of MYTHIC trial evaluating lunresertib in combination with Debio 0123 (WEE1 inhibitor)

Cash Position and Financial Guidance:

Repare ended 2024 with approximately $153 million in cash, cash equivalents and marketable securities, which is anticipated with the implementation of the cost-saving measures announced above to fund the Company's streamlined operations into mid-2027.

About Repare Therapeutics Inc.

Repare Therapeutics is a leading clinical-stage precision oncology company enabled by its proprietary synthetic lethality approach to the discovery and development of novel therapeutics. The Company utilizes its genome-wide, CRISPR-enabled SNIPRx® platform to systematically discover and develop highly targeted cancer therapies focused on genomic instability, including DNA damage repair. The Company's clinical-stage pipeline includes RP-1664, a Phase 1 PLK4 inhibitor; RP-3467, a Phase 1 Polθ ATPase inhibitor; and lunresertib, a PKMYT1 inhibitor, and camonsertib, a potential leading ATR inhibitor. For more information, please visit reparerx.com and follow @Reparerx on X (formerly Twitter) and LinkedIn.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and securities laws in Canada. All statements in this press release other than statements of historical facts are "forward-looking statements. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements regarding: the Company's plans for re-prioritization of its portfolio and the implementation of other cost saving measures, and the expected impact of such actions; the Company's preliminary unaudited balance of cash, cash equivalents and marketable securities as of the end of 2024 and the Company's anticipated cash runway; the Company's plans to secure a partner to fund further clinical development of camonsertib and lunresertib; the potential, tolerability, efficacy and clinical progress of the Company's product candidates; and the design, objectives, initiation, timing, progress and results of current and future preclinical studies and clinical trials of the Company's product candidates. These forward-looking statements are based on the Company's expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties that could cause the Company's clinical development programs, future results or performance to differ materially from those expressed or implied by the forward-looking statements. Many factors may cause differences between current expectations and actual results, including: the potential that success in preclinical testing and earlier clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate; the impacts of macroeconomic conditions, including the conflict in Ukraine and the conflict in the Middle East, fluctuations in inflation and uncertain credit and financial markets, on the Company's business, clinical trials and financial position; unexpected safety or efficacy data observed during preclinical studies or clinical trials; clinical trial site activation or enrollment rates that are lower than expected; the Company's ability to realize the benefits of its collaboration and license agreements; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; and unexpected litigation or other disputes. Other factors that may cause the Company's actual results to differ from those expressed or implied in the forward-looking statements in this press release are identified in the section titled "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 filed with the Securities and Exchange Commission ("SEC") and the Québec Autorité des Marchés Financiers ("AMF") on November 7, 2024. The Company expressly disclaims any obligation to update any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise, except as otherwise required by law. For more information, please visit reparerx.com and follow Repare on X (formerly Twitter) at @RepareRx and on LinkedIn at https://www.linkedin.com/company/repare-therapeutics/.

Preliminary Financial Information

Repare's audited consolidated financial statements at and for the year ended December 31, 2024 are not yet available. As a result, the financial information described in this press release is preliminary and unaudited, represents management's estimate as of the date hereof and is subject to completion of Repare's financial closing procedures for the fourth quarter and fiscal year ended December 31, 2024. This preliminary financial information may materially differ from the actual results that will be reflected in Repare's audited consolidated financial statements when such financial statements are completed and publicly disclosed. Repare's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, Repare's preliminary results.

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