Repare Therapeutics Provides Business Update and Reports Third Quarter 2023 Financial Results

November 9, 2023

Presented positive initial data from ongoing Phase 1 MYTHIC clinical trial evaluating lunresertib alone and in combination with camonsertib, including an overall RECIST response rate of 50% in patients with heavily pre-treated gynecological tumors

Repare to host conference call and webcast to discuss latest data from its preclinical programs and overall pipeline, November 15th, 2023 at 8:00 a.m. ET

CAMBRIDGE, Mass. & MONTREAL--(BUSINESS WIRE)--Nov. 9, 2023-- Repare Therapeutics Inc. (“Repare” or the “Company”) (Nasdaq: RPTX), a leading clinical-stage precision oncology company, today reported financial results for the third quarter ended September 30, 2023.

“We substantially advanced our pipeline during the third quarter, particularly our Phase 1 MYTHIC trial evaluating lunresertib as a monotherapy and in combination with camonsertib. The initial data that was presented in a plenary session at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2023 showed early efficacy signals across multiple tumor types and in each genotype selected, most notably in gynecological tumors, along with a favorable safety and tolerability profile,” said Lloyd M. Segal, President and Chief Executive Officer of Repare. “Additionally, we look forward to hosting an investor event focused on our preclinical programs, RP-1664 and RP-3467, next week, on November 15th, where we will showcase the strength of our growing pipeline.”

Third Quarter 2023 Review and Operational Updates:

- **Advancing lunresertib (RP-6306), a first-in-class, oral PKMYT1 inhibitor, for the treatment of molecularly selected advanced solid tumors.**
- Presented initial positive data from Modules 1 and 2 of its ongoing Phase 1 MYTHIC trial evaluating lunresertib alone and in combination with camonsertib in patients with advanced solid tumors harboring *CCNE1* amplification or *FBXW7* or *PPP2R1A* deleterious alternations (NCT04855656) at the 2023 AACR-NCI-EORTC International Conference and additional data from a later cut-off date in a virtual webcast event hosted by Repare.
    - As of the September 5, 2023 data cut-off date as presented during the company virtual webcast event, the Company reported that 67 patients were enrolled in Module 1 (monotherapy) and 59 patients in Module 2 (combination therapy).
    - In the Module 2 cohort at the combination preliminary recommended Phase 2 dose (RP2D):
- Protocol-defined overall response (OR) (RECIST or GCIG CA-125 responses) was observed to be 33.3% (N=18). Clinical benefit rate (CBR) (overall response or stable disease of at least 16 weeks without tumor progression) was 50.0%.
- In the cohort of patients with gynecologic tumors, the RECIST response was 50%, OR was 60%, and CBR was 70%. These patients also had a median of 3 and up to 9 prior lines of therapy, before administration of lunresertib.
    - In all evaluable patients in the trial, across all doses (N=55), OR was 23.6% and CBR was 41.8%.
    - RECIST responses in this ongoing combination trial included 8 confirmed and 3 unconfirmed partial responses (PR). Additionally, 3 patients with ovarian tumors had cancer antigen 125 (CA-125) responses.
    - Encouraging and highly manageable safety and tolerability was observed for the combination therapy arm of the trial (N=59). The most common treatment-related adverse event (TRAE) was anemia, with Grade 3 occurring in 42% of patients enrolled in the trial:
- 35% of patients did not develop anemia at the preliminary RP2D. Generally, those with Grade 3 anemia had the lowest hemoglobin values at the time of trial enrollment, were intensely pretreated with greater than 4 prior therapies and were of advanced age.
- The anemia reported by patients in the trial usually improved after a one-week treatment interruption and standard supportive care, and did not lead to any therapy discontinuations for patients who received treatment at the preliminary RP2D.
- There were no Grade 4 or Grade 5 TRAEs reported at the preliminary RP2D.
- This data indicates that anemia management can be individualized and alleviated with simple patient monitoring. This approach is now being tested in the expansion cohorts of the MYTHIC trial.
    - Repare expects to report additional combination therapy data from the expansion cohorts of the MYTHIC trial in the second half of 2024.
- Repare expects to report initial data from its ongoing Phase 1 MINOTAUR trial evaluating lunresertib in combination with FOLFIRI (NCT05147350) in the first half of 2024. Additionally, the Company expects to report initial updated data from its ongoing Phase 1 MAGNETIC trial evaluating lunresertib in combination with gemcitabine (NCT05147272) in the second half of 2024.
- Repare is collaborating with Princess Margaret Cancer Center to initiate clinical testing, as part of an investigator-sponsored trial (IST), of a fourth lunresertib combination with carboplatin and paclitaxel for the treatment of recurrent gynecological malignancies, with first patient dosing expected to take place by the end of this year.

- Repare is also collaborating with the Canadian Cancer Trials Group in an ongoing basket Phase 2 IST that is enrolling patients with selected, advanced cancers receiving lunresertib as combination with gemcitabine (NCT05605509), and in a second active trial that will evaluate lunresertib in combination with gemcitabine in patients with CDK4/6 inhibitor treated ER+/HER2- metastatic breast cancer (NCT05601440).
- **Advancing camonsertib (RP-3500 / RG6526), a potent and selective oral small molecule inhibitor of ATR (Ataxia-Telangiectasia and Rad3-related protein kinase) for the treatment of tumors with specific synthetic lethal genomic alterations in partnership with Roche.**
- Roche has included a camonsertib-based arm in its Phase 2, global, multicenter, open-label, multi-cohort TAPISTRY trial (NCT04589845) and its Phase 1/2 study of multiple immunotherapy-based treatment combinations in participants with metastatic non-small cell lung cancer (Morpheus Lung; NCT03337698). Repare is eligible to receive a milestone payment of $40 million upon enrollment of the first patient with camonsertib in the TAPISTRY trial, which is expected by year-end, and could be eligible for an additional $15 million milestone payment if this study becomes registrational.
- Repare is continuing to conduct dose optimization and efficacy assessments in tumor specific expansions in the ATTACC clinical trial in collaboration with Roche to support future clinical development plans for camonsertib combinations with PARP inhibitors.
- Repare also presented clinical and preclinical data from its ongoing Phase 1b TRESR clinical trial evaluating camonsertib in combination with gemcitabine in patients with solid tumors with ATR inhibitor sensitizing mutations at the AACR-NCI-EROTC conference. The latest data cut from the trial continues to show the benefits of combination therapy, which has led to anti-tumor activity in heavily pretreated patients, including 7 patients (N=28) with confirmed or unconfirmed PRs per RECIST, or GCIG CA-125 responses (N=28), with responses observed primarily in patients with gynecologic cancers. Overall molecular response rate (MRR) of 57%, along with 82% decrease in circulating tumor DNA (ctDNA). The combination therapy was found to be safe and well-tolerated to date, with no drug-drug interactions observed. Efficacy assessment is ongoing at the proposed RP2D in patients with ovarian cancer.
- **Advancing preclinical programs into clinical development.**
- RP-1664 IND-enabling studies, which began in the first quarter of 2023, are nearing completion and Repare expects to initiate a clinical trial in the first half of 2024.
- RP-3467 is Repare's wholly-owned Polθ inhibitor, currently in IND-enabling studies, which began in the second quarter of 2023 and remain ongoing. Repare expects to initiate a clinical trial in the second half of 2024.

Third Quarter 2023 Financial Results:

- **Cash and cash equivalents and marketable securities:** Cash and cash equivalents and marketable securities as of September 30, 2023 were $250.1 million, which Repare believes will be sufficient to fund its planned operations into 2026.
- **Revenue from collaboration agreements:** Revenue from collaboration agreements were $2.2 million and $38.1 million for the three and nine months ended September 30, 2023, respectively, as compared to $112.5 million and $113.6 million for the three and nine months ended September 30, 2022. The decrease in revenue for the three- and nine-month periods were primarily due to a decrease in revenue recognized under the Roche collaboration mainly as a result of the $108.0 million revenue recognized in the third quarter of 2022 pursuant to the satisfaction of our performance obligations for the issuance of the combined licenses and the clinical trial materials transferred. The decrease in the nine-month period was partially offset by higher deferred revenue recognized from the Roche collaboration, the BMS collaboration and the Ono collaboration.
- **Research and development expenses, net of tax credits (Net R&D):** Net R&D expenses were $32.7 million and $98.3 million for the three and nine months ended September 30, 2023, respectively, as compared to $31.2 million and $89.2 million for the three and nine months ended September 30, 2022. The increase in Net R&D expenses for the three- and nine-month periods were primarily due to higher personnel-related costs and direct external costs related to the progress of our lunresertib clinical program, as well as the advancement of preclinical programs into IND-enabling studies.
- **General and administrative (G&A) expenses:** G&A expenses were $7.9 million and $25.1 million for the three and nine months ended September 30, 2023, respectively, compared to $7.9 million and $24.6 million for the three and nine months ended September 30, 2022. The increase in G&A was primarily due to higher personnel related costs, offset by lower D&O insurance premiums and lower professional fees.
- **Net income (loss):** Net loss was $18.9 million, or $0.45 per share, and $65.8 million, or $1.56 per share, in the three and nine months ended September 30, 2023, respectively, and net income was $75.5 million, or $1.71 per share, and $2.6 million, or $0.06 per share, in the three and nine months ended September 30, 2022, respectively.

About Repare Therapeutics' SNIPRx® Platform

Repare's SNIPRx® platform is a genome-wide CRISPR-based screening approach that utilizes proprietary isogenic cell lines to identify novel and known synthetic lethal gene pairs and the corresponding patients who are most likely to benefit from the Company's therapies based on the genetic profile of their tumors. Repare's platform enables the development of precision therapeutics in patients whose tumors contain one or more genomic alterations identified by SNIPRx® screening, in order to selectively target those tumors in patients most likely to achieve clinical benefit from resulting product candidates.

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 pipeline includes lunresertib (also known as RP-6306), a PKMYT1 inhibitor currently in Phase 1 clinical development; camonsertib (also known as RP-3500 or RG6526), a potential leading ATR inhibitor currently in Phase 1/2 clinical development and partnered with Roche; RP-3467, a preclinical Polθ inhibitor program; as well as several additional, undisclosed preclinical programs, including RP-1664. For more information, please visit reparerx.com and follow @Reparerx on X (formerly Twitter) and LinkedIn.

SNIPRx® is a registered trademark of Repare Therapeutics Inc.

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 initiation, timing, progress and results of the Company's current and future preclinical studies and clinical trials and related preparatory work and the period during which the results of the trials will become available, as well as our research and development programs; the safety, efficacy and clinical progress of the Company's clinical programs, including specifically the continued further development of lunresertib (also known as RP-6306) and camonsertib; the timing of the expected combination therapy data from the expansion cohorts of the MYTHIC trial; the timing of availability or disclosure of data from the other clinical trials of lunresertib (also known as RP-6306) and camonsertib as well as the Phase 1 MINOTAUR trial and ongoing IST studies; the anticipated initiation of clinical trials of RP-1664 and RP-3467; the ability for the TAPISTRY trial to be deemed a registrational trial; the Company's ability to enroll patients in clinical trials, to timely and successfully complete those trials and to receive necessary regulatory approvals; the timing of planned regulatory submissions for lunresertib, camonsertib or the Company's other product candidates; the potential for lunresertib, camonsertib or the Company's other product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies; and the Company's ability to achieve milestones and receive associated milestone payments pursuant to the terms of its collaboration agreements, including pursuant to the Roche collaboration. 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: 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 COVID-19 pandemic, the conflict in Ukraine, the Hamas-Israel conflict, rising 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; 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 Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission ("SEC") and the Québec Autorité des Marchés Financiers ("AMF") on February 28, 2023, and its other documents subsequently filed with or furnished to the SEC and AMF, including the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 9, 2023. 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 Twitter at @RepareRx and on LinkedIn at https://www.linkedin.com/company/repare-therapeutics/.

Repare Therapeutics Inc.

Condensed Consolidated Balance Sheets

(Unaudited)

(Amounts in thousands of U.S. dollars, except share data)

	As of September 30, 2023	As of December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 107,369	$ 159,521

Marketable securities	142,703	184,420
Income tax receivable	15,739	—
Other current receivables	3,731	4,323
Prepaid expenses	5,551	5,715
Total current assets	275,093	353,979
Property and equipment, net	4,722	4,228
Operating lease right-of-use assets	3,883	5,371
Income tax receivable	2,312	—
Other assets	397	497
TOTAL ASSETS	$ 286,407	$ 364,075
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,438	$ 461
Accrued expenses and other current liabilities	20,729	21,645
Operating lease liability, current portion	2,333	2,171
Deferred revenue, current portion	20,472	53,102
Income tax payable	—	1,240
Total current liabilities	48,972	78,619
Operating lease liability, net of current portion	1,591	3,257
Deferred revenue, net of current portion	2,476	2,682
TOTAL LIABILITIES	53,039	84,558
SHAREHOLDERS' EQUITY		
Preferred shares, no par value per share; unlimited shares authorized as of September 30, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding as of September 30, 2023, and December 31, 2022, respectively	—	—
Common shares, no par value per share; unlimited shares authorized as of September 30, 2023 and December 31, 2022; 42,129,251 and 42,036,193 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	483,184	482,032
Additional paid-in capital	55,515	37,226

Accumulated other comprehensive loss	(252)	(428)
Accumulated deficit	(305,079)	(239,313)
Total shareholders' equity	233,368	279,517
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 286,407	$ 364,075

Repare Therapeutics Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited)

(Amounts in thousands of U.S. dollars, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Collaboration agreements	$ 2,159	$ 112,545	$ 38,086	$ 113,632
Operating expenses:				
Research and development, net of tax credits	32,709	31,242	98,327	89,175
General and administrative	7,868	7,904	25,116	24,621
Total operating expenses	40,577	39,146	123,443	113,796
(Loss) income from operations	(38,418)	73,399	(85,357)	(164)
Other income (expense), net				
Realized and unrealized (loss) gain on foreign exchange	(40)	126	(137)	250
Interest income	3,312	2,027	10,228	2,700
Other expense	(32)	(37)	(73)	(56)
Total other income, net	3,240	2,116	10,018	2,894
(Loss) income before income taxes	(35,178)	75,515	(75,339)	2,730
Income tax recovery (expense)	16,299	(54)	9,573	(119)
Net (loss) income	$ (18,879)	$ 75,461	$ (65,766)	$ 2,611
Other comprehensive (loss) gain:				

Unrealized gain (loss) on available-for-sale marketable securities	$ 172	$ (524)	$ 176	$ (524)
Total other comprehensive gain (loss)	172	(524)	176	(524)
Comprehensive (loss) income	$ (18,707)	$ 74,937	$ (65,590)	$ 2,087
Net (loss) income per share attributable to common shareholders:				
Basic	$ (0.45)	$ 1.80	$ (1.56)	$ 0.06
Diluted	$ (0.45)	$ 1.71	$ (1.56)	$ 0.06
Weighted-average common shares outstanding:				
Basic	42,102,685	41,945,617	42,077,857	41,902,554
Diluted	42,102,685	44,177,376	42,077,857	44,160,481

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