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

August 9, 2023

Presented initial camonsertib-PARPi combination Phase 1/2 clinical data at AACR 2023 demonstrating durable clinical benefit across tumor types, genomic alterations, PARPi choice or platinum resistance

Roche has included a camonsertib-based arm in its Phase 2 TAPISTRY study and its Phase 1/2 Morpheus Lung study of multiple combinations in metastatic non-small cell lung cancer

Reported clinical proof of concept for lunresertib (RP-6306) in June 2023 including achievement of monotherapy safety and tolerability primary endpoints and identification of two proposed dose/schedules

Presented early lunresertib combination response data in June 2023, and expects to present further Phase 1 MYTHIC Module 2 data at a medical conference in the fourth quarter of this year

Granted FDA Fast Track designation for lunresertib in combination with camonsertib for the treatment of adult patients with CCNE1 amplified, or FBXW7 or PPP2R1A mutated endometrial cancer in August

Initiated IND-enabling studies for newly designated Polθ inhibitor RP-3467

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

“During the second quarter we made great progress advancing our clinical programs and presenting novel findings from our ongoing clinical trials, including reporting on camonsertib’s combination with three PARP inhibitors and initial clinical proof of concept for lunresertib,” said Lloyd M. Segal, President and Chief Executive Officer of Repare. “While these clinical programs move towards Phase 2 studies, we continue to support our preclinical pipeline, for example with the designation of our Polθ inhibitor, RP-3467. We look forward to reporting initial combination data of lunresertib with camonsertib in the fourth quarter of this year as we continue advancing our differentiated, synthetic lethal-based oncology pipeline.”

Second Quarter 2023 Review and Operational Updates:

- **Advancing camonsertib, 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 study (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 dosing of the first patient with camonsertib in the TAPISTRY study and could be eligible for an additional $15 million milestone if this study becomes registrational.
  - Repare is continuing to conduct dose optimization and efficacy assessments in tumor specific expansions in the ATTACC study in collaboration with Roche to support future clinical development plans for camonsertib combinations with PARP inhibitors. In April 2023, we received a payment of $4 million from Roche for additional revisions to the clinical development plan under the Roche Agreement. Repare is eligible to receive further milestone payments upon the initiation of registrational trials or the transition of existing trials to become registrational for camonsertib in specific tumor types.
  - Published data in *Nature Medicine* from the ongoing Phase 1/2 TRESR clinical trial evaluating camonsertib monotherapy in 120 patients (NCT04497116). The article, entitled “Camonsertib in DNA damage response-deficient advanced solid tumors: phase 1 trial results” can be accessed here.
  - Announced initial clinical data from the Phase 1/2 TRESR and ATTACC trials evaluating camonsertib in combination with three poly (ADP-ribose) polymerase (PARP) inhibitors in a Clinical Trials Plenary Session at the 2023 American Association for Cancer Research (AACR) Annual Meeting.
  - Camonsertib-PARP inhibitor combinations appeared to be well tolerated and resulted in durable clinical benefit across tumor types and genomic alterations, regardless of choice of PARP inhibitor and presence of platinum resistance. Overall clinical benefit rate (CBR) for all patients was 48%. Patients with platinum-resistant tumors had an overall response rate (ORR) of 12% and CBR of 49% and benefited similarly to non-platinum-resistant tumors (ORR 13%, CBR 46%). Compelling results were observed particularly in patients with advanced ovarian cancer (n = 19), including overall response of 32%, CBR of 58% and median progression-free survival of approximately 7 months with treatment greater than 16 weeks and ongoing in 9 patients, as of the 2023 AACR Annual Meeting data cutoff of February 27, 2023. The molecular response rate (MRR) of circulating tumor DNA was significantly higher in patients with clinical benefit (83%) compared to those without (48%; p=0.015) and significantly higher than seen in the camonsertib monotherapy trial in which camonsertib was administered at higher doses (66% vs. 43%; p=0.02). Molecular responses were also observed in patients with prior PARP inhibitor exposure (57%) and

platinum resistance (64%).

- **Advancing lunresertib (RP-6306), a first-in-class, oral PKMYT1 inhibitor, for the treatment of molecularly select advanced solid tumors as a monotherapy and in combinations in multiple clinical studies.**
    - Announced clinical proof of concept for lunresertib, including monotherapy data from the Phase 1 MYTHIC clinical trial and early insights from ongoing combination trials in June 2023. Achieved primary endpoints of safety and tolerability and proposed dose and schedule. The tolerability profile of lunresertib monotherapy appears favorable and differentiated from other clinical cell cycle inhibitors, as lunresertib treatment does not result in significant myelotoxicity nor diarrhea. No grade 4 toxicity was observed with lunresertib, while grade 3 treatment emergent adverse events of interest included rash (7.9%), anemia (6.3%) and nausea or vomiting (1.6%). The dose limiting toxicity was reversible rash, alleviated with dose modifications and simple supportive measures. Two proposed dose/schedules were identified – 240mg daily continuously and 80-100mg BID intermittent weekly – to offer maximum flexibility in combination studies.
    - Preliminary anti-tumor activity was observed for monotherapy, including moderate tumor shrinkages and a confirmed partial response per RECIST 1.1 criteria in a patient with metastatic recurrent uterine carcinosarcoma.
    - Early clinical responses per RECIST 1.1 criteria have been observed with lunresertib and combinations with gemcitabine, camonsertib, and FOLFIRI in multiple tumor types and genotypes.
    - 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 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 study that will evaluate lunresertib in combination with gemcitabine in patients with CDK4/6 inhibitor treated ER+/HER2- metastatic breast cancer (NCT05601440).
    - In August 2023, the U.S. Food and Drug Administration (FDA) granted Fast Track designation (FTD) to lunresertib in combination with camonsertib for the treatment of adult patients with CCNE1 amplified, or FBXW7 or PPP2R1A mutated endometrial cancer previously treated with a platinum-containing regimen and immune checkpoint inhibitor when indicated. FTD is intended to facilitate the development and expedite the review of drugs to treat serious conditions and fulfill an unmet medical need, enabling drugs to reach patients earlier.
    - The Company expects to present further Phase 1 MYTHIC Module 2 combination data with camonsertib at a medical conference in the fourth quarter of this year.
- **Advancing preclinical programs into clinical development.**
    - RP-1664 IND-enabling studies, which began in the first quarter of 2023, remain ongoing with potential for the program to enter the clinic in early 2024.
    - Initiated IND-enabling studies for the newly designated Polθ inhibitor RP-3467 in June 2023. RP-3467 has shown greater potency in preclinical studies compared to RP-2119, our first Polθ inhibitor designated in 2022, and has potential to enter the clinic in 2024. The research term of our Polθ collaboration with Ono Pharmaceutical Company Ltd., as previously extended, expired on July 31, 2023. With the termination of the agreement with Ono Pharmaceutical Company Ltd., Repare's Polθ program, including RP-3467, is wholly-owned by Repare.
- **The Company intends to host an R&D day focused on its ongoing pre-clinical programs and its overall pipeline in the fourth quarter of this year.**
- **In May 2023, Bristol Myers Squibb exercised its option for a third druggable target and separately triggered a $1 million payment for a previously exercised druggable target option.**

Second Quarter 2023 Financial Results:

- **Cash and cash equivalents and marketable securities:** Cash and cash equivalents and marketable securities as of June 30, 2023 were $280.7 million, which Repare believes will be sufficient to fund its planned operations into 2026.
- **Revenue from collaboration agreements:** Revenue from collaboration agreements were $30.2 million and $35.9 million for the three and six months ended June 30, 2023, respectively, as compared to $0.7 million and $1.1 million for the three and six months ended June 30, 2022. The increase in revenue for the three- and six-month periods were primarily due to revenue recognized from our collaboration and license agreement with BMS and our collaboration agreement with Ono.
- **Research and development expenses, net of tax credits (Net R&D):** Net R&D expenses were $33.8 million and $65.6 million for the three and six months ended June 30, 2023, respectively, as compared to $31.5 million and $57.9 million for the three and six months ended June 30, 2022. The increase in Net R&D expenses for the three- and six-month periods was primarily due to higher personnel-related costs and direct external costs related to the advancement of preclinical programs into IND-enabling studies.
- **General and administrative (G&A) expenses:** G&A expenses were $8.7 million and $17.2 million for the three and six months ended June 30, 2023, respectively, compared to $7.9 million and $16.7 million for the three and six months ended June 30, 2022. The increase in G&A was primarily due higher personnel related costs, offset by lower D&O insurance premiums.

- **Net loss:** Net loss was $11.9 million, or $0.28 per share, and $46.9 million, or $1.11 per share, in the three and six months ended June 30, 2023, respectively, and $38.1 million, or $0.91 per share, and $72.9 million, or $1.74 per share, in the three and six months ended June 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.

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 safety, efficacy and clinical progress of the Company's clinical programs, including lunresertib (RP-6306) and camonsertib; the clinical and preclinical development of the Company's pipeline and its research and development programs, including the anticipated timing, anticipated patient enrollment, trial outcomes or associated costs of its clinical trials of lunresertib and camonsertib; and the status of clinical trials (including, without limitation, expectations regarding the data that is being presented, the expected timing of data releases and development, as well as completion of clinical trials) and development timelines for 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 impacts of macroeconomic conditions, including the COVID-19 pandemic, the conflict in Ukraine, 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. 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 June 30, 2023	As of December 31, 2022
ASSETS		
CURRENT ASSETS:		

Cash and cash equivalents	$ 115,544	$ 159,521
Marketable securities	165,148	184,420
Income tax receivable	1,751	—
Other current receivables	5,281	4,323
Prepaid expenses	4,201	5,715
Total current assets	291,925	353,979
Property and equipment, net	4,821	4,228
Operating lease right-of-use assets	4,434	5,371
Other assets	408	497
TOTAL ASSETS	$ 301,588	$ 364,075
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 4,893	$ 461
Accrued expenses and other current liabilities	21,628	21,645
Operating lease liability, current portion	2,320	2,171
Deferred revenue, current portion	24,412	53,102
Income tax payable	—	1,240
Total current liabilities	53,253	78,619
Operating lease liability, net of current portion	2,226	3,257
Deferred revenue, net of current portion	695	2,682
TOTAL LIABILITIES	56,174	84,558
SHAREHOLDERS' EQUITY		
Preferred shares, no par value per share; unlimited shares authorized as of June 30, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding as of June 30, 2023, and December 31, 2022, respectively	—	—
Common shares, no par value per share; unlimited shares authorized as of June 30, 2023 and December 31, 2022; 42,093,946 and 42,036,193 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	482,739	482,032
Additional paid-in capital	49,299	37,226

Accumulated other comprehensive loss	(424)	(428)
Accumulated deficit	(286,200)	(239,313)
Total shareholders' equity	245,414	279,517
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$ 301,588	$ 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 June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Collaboration agreements	$ 30,249	$ 679	$ 35,927	$ 1,087
Operating expenses:				
Research and development, net of tax credits	33,788	31,475	65,618	57,933
General and administrative	8,719	7,938	17,248	16,717
Total operating expenses	42,507	39,413	82,866	74,650
Loss from operations	(12,258)	(38,734)	(46,939)	(73,563)
Other income (expense), net				
Realized and unrealized (loss) gain on foreign exchange	(41)	141	(97)	124
Interest income	3,489	544	6,916	673
Other expense	(26)	(11)	(41)	(19)
Total other income, net	3,422	674	6,778	778
Loss before income taxes	(8,836)	(38,060)	(40,161)	(72,785)
Income tax expense	(3,110)	(33)	(6,726)	(65)
Net loss	$ (11,946)	$ (38,093)	$ (46,887)	$ (72,850)
Other comprehensive (loss) gain:				

Unrealized (loss) gain on available-for-sale marketable securities	$ (189)	$ —	$ 4	$ —
Total other comprehensive (loss) gain	(189)	—	4	—
Comprehensive loss	$ (12,135)	$ (38,093)	$ (46,883)	$ (72,850)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.28)	$ (0.91)	$ (1.11)	$ (1.74)
Weighted-average common shares outstanding - basic and diluted	42,089,530	41,899,509	42,065,237	41,880,666

View source version on businesswire.com: https://www.businesswire.com/news/home/20230809252741/en/

Repare Contact:
Steve Forte
Executive Vice-President and Chief Financial Officer
Repare Therapeutics Inc.
investor@reparerx.com

Investors:
Matthew DeYoung
Argot Partners
repare@argotpartners.com

Media:
David Rosen
Argot Partners
david.rosen@argotpartners.com
212-600-1902

Source: Repare Therapeutics Inc.