

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 28, 2023

Repare Therapeutics Inc.

(Exact name of Registrant as Specified in Its Charter)

Quebec
(State or Other Jurisdiction
of Incorporation)

001-39335
(Commission File Number)

Not applicable
(IRS Employer
Identification No.)

7210 Frederick-Banting, Suite 100
St-Laurent, Quebec, Canada
(Address of Principal Executive Offices)

H4S 2A1
(Zip Code)

Registrant's Telephone Number, Including Area Code: 857 412-7018

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, no par value	RPTX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On February 28, 2023, Repare Therapeutics Inc. (the "Company") issued a press release announcing its recent business highlights and financial results for the three and twelve months ended December 31, 2022. A copy of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section. The information contained herein and in the accompanying exhibit is not incorporated by reference in any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit

No.	Description
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99.1	Press Release dated February 28, 2023
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104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

REPARE THERAPEUTICS INC.

Date: February 28, 2023

By: /s/ Lloyd M. Segal

Lloyd M. Segal

President and Chief Executive Officer



Repare Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2022 Financial Results

CAMBRIDGE, Mass. & MONTREAL (BUSINESS WIRE)—February 28, 2023— Repare Therapeutics Inc. (“Repare” or the “Company”) (Nasdaq: RPTX), a leading clinical-stage precision oncology company, today reported financial results for the fourth quarter and full year ended December 31, 2022.

“We made substantial progress advancing our innovative, synthetic lethality-based pipeline across multiple programs in 2022, including entering into a worldwide collaboration agreement with Roche to develop camonsertib, receiving Fast Track designation from the FDA for our first-in-class PKMYT1 inhibitor RP-6306, and advancing our preclinical programs,” said Lloyd M. Segal, President and Chief Executive Officer of Repare. “We expect 2023 to be another productive year for Repare across the portfolio, with early clinical readouts for both camonsertib and RP-6306 in the first half of 2023. In addition, we are poised to expand our pipeline leveraging our proprietary SNIPRx platform, and look forward to sharing more information on our third clinical program this summer.”

2022 Highlights and 2023 Outlook:

- **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.**
 - o Initial data from the Phase 1/2 trials evaluating camonsertib in combination with three poly (ADP-ribose) polymerase (PARP) inhibitors is expected to be presented in the first half of 2023 at a major medical meeting.
 - o The Company expects to report initial data from the Phase 1/2 TRESR trial evaluating camonsertib in combination with gemcitabine in the summer or fall of 2023.
 - **Evaluating RP-6306, a first-in-class, oral PKMYT1 inhibitor as a monotherapy and in combinations in multiple early clinical studies.**
 - o The Company expects to report initial Phase 1 clinical data for RP-6306 as a monotherapy for the treatment of molecularly selected advanced solid tumors (MYTHIC) in the first half of 2023. The Company expects to report initial Phase 1 clinical data for RP-6306 as a combination therapy for the treatment of molecularly selected advanced solid tumors in the fourth quarter of 2023.
 - o In the fourth quarter of 2022, the U.S. Food and Drug Administration (FDA) granted Fast Track designation (FTD) to RP-6306 in combination with gemcitabine for the treatment of adult patients with CCNE1 amplified, or FBXW7 or PPP2R1A mutated platinum resistant ovarian cancer. 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.
 - o Based on promising preclinical data released at the 34th EORTC-NCI-AACR Symposium in October 2022, Repare is working with clinical investigators to initiate clinical testing, as part of an investigator-sponsored trial (IST), of a fourth new RP-6306 combination with carboplatin, with first patient dosing expected in the first half of 2023.
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- o In the fourth quarter of 2022, Repare entered into an agreement with Canadian Cancer Trials Group (CCTG) for a planned, basket Phase 2 IST to evaluate RP-6306 in patients with selected, advanced cancers receiving standard agents. A sub-study under the master clinical trial protocol will evaluate RP-6306 in combination with gemcitabine in patients with CD4/6i-resistant ER+/HER2- metastatic breast cancer.
- **Advancing preclinical programs into clinical development.**
 - o Repare expects to initiate IND-enabling studies in the first half of 2023 for a small molecule against an undisclosed target with potential to enter the clinic in late 2023 or early 2024, which represents an acceleration from the Company's prior expectations for this program.
 - o Repare is pursuing development of an inhibitor of polymerase theta (Polθ) in collaboration with Ono Pharmaceutical Company Ltd (Ono) in Japan, South Korea, Taiwan, Hong Kong, Macau and ASEAN countries, excluding mainland China. Repare retains all rights to develop and commercialize the products outside the Ono territory. In 2022, the Company selected a proposed inhibitor of Polθ, which it designated as RP-2119. In February 2023, based on its review of ongoing preclinical studies, Repare elected to prioritize other Polθ inhibiting compounds in its preclinical development portfolio, which it believes have a higher probability for clinical impact relative to RP-2119. The Company is now guiding toward clinical entry for a Polθ inhibitor in 2024.
 - o In January 2023, Repare received an approximate \$1.5 million (¥200 million) milestone payment from Ono. The payment reflected the achievement of a research milestone under the Company's research services, license and collaboration agreement with Ono (Ono Agreement).
 - o Also in January 2023, Repare and Ono amended the Ono Agreement to further extend the research term until July 31, 2023. Previously, Repare had entered into an amendment with Ono in October 2021 to extend the research term by one year at no additional cost to Repare.

Fourth Quarter and Full Year 2022 Financial Results:

- **Cash and cash equivalents and marketable securities:** Cash and cash equivalents and marketable securities as of December 31, 2022 were \$343.9 million, which Repare believes will be sufficient to fund its planned operations into 2026.
 - **Revenue from collaboration agreements:** Revenue from collaboration agreements were \$18.2 million and \$131.8 million for the three- and twelve-month periods ended December 31, 2022, respectively, as compared to \$6.9 million and \$7.6 million for the three- and twelve-month periods ended December 31, 2021, due to revenue recognized from our collaboration and license agreement with Roche.
 - **Research and development expenses, net of tax credits (Net R&D):** Net R&D expenses were \$29.9 million and \$119.1 million for the three- and twelve-month periods ended December 31, 2022, respectively, as compared to \$28.0 million and \$90.0 million for the three- and twelve-month periods ended December 31, 2021 due to an increase in development activities related to the advancement of the RP-6306 program and preclinical activities related to pipeline programs; an increase of personnel-related costs, including share-based compensation, for increased headcount in support of discovery and development activities; and other research and development costs. Camonsertib costs were similar on a year over year basis and decreased quarter over quarter following the transfer of CMC related activities to Roche pursuant to the collaboration agreement.
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- **General and administrative (G&A) expenses:** G&A expenses were \$7.9 million and \$32.6 million for the three- and twelve-month periods ended December 31, 2022, respectively, as compared to \$7.6 million and \$26.2 million for the three- and twelve-month periods ended December 31, 2021. The increase in G&A expenses for the three- and twelve-month periods were primarily due to higher personnel related costs, including share-based compensation; an increase in professional fees associated with the Roche collaboration agreement and the establishment of our at-the-market (ATM) offering, as well as timing of audit and SOX compliance efforts, partially offset by a decrease in our D&O insurance premium.
- **Net loss:** Net loss was \$31.7 million, or \$0.75 per share, and \$29.0 million, or \$0.69 per share, for the three- and twelve-month periods ended December 31, 2022, respectively, and \$28.3 million, or \$0.70 per share and \$106.9 million, or \$2.83 per share, for the three- and twelve-month periods ended December 31, 2021, 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 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; a preclinical Polθ inhibitor program; as well as several additional, undisclosed preclinical programs. 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 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 RP-6306 and camonsertib and ongoing preclinical studies of the Company's Polθ inhibitor program; the Company's continued development of camonsertib in partnership with Roche; 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; selection of a Polq inhibiting compound and the Company's plans and timing with respect to an IND filing for its Polq program; the sufficiency of the Company's cash resources and its anticipated cash runway into 2026; and the expected benefits of the Company's collaborations and partnerships. 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.
Consolidated Balance Sheets
(Unaudited)
(Amounts in thousands of U.S. dollars, except share data)

	As of December 31,	
	2022	2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 159,521	\$ 334,427
Marketable securities	184,420	7,439
Research and development tax credits receivable	1,280	2,580
Collaboration revenue receivable	1,525	—
Other receivables	1,518	654
Prepaid expenses	5,715	6,314
Total current assets	353,979	351,414
Property and equipment, net	4,228	5,604
Operating lease right-of-use assets	5,371	7,491
Other assets	497	586
Deferred tax assets	—	3,620
TOTAL ASSETS	\$ 364,075	\$ 368,715
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 461	\$ 2,302
Accrued expenses and other current liabilities	21,645	18,622
Operating lease liabilities, current portion	2,171	1,721
Deferred revenue, current portion	53,102	11,921
Income tax payable	1,240	523
Total current liabilities	78,619	35,089
Operating lease liabilities, net of current portion	3,257	5,592
Deferred revenue, net of current portion	2,682	39,613
TOTAL LIABILITIES	84,558	80,294
Commitments and Contingencies		
SHAREHOLDERS' EQUITY:		
Preferred shares, no par value per share; unlimited shares authorized as of December 31, 2022 and December 31, 2021, respectively; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	—	—
Common shares, no par value per share; unlimited shares authorized as of December 31, 2022 and December 31, 2021; 42,036,193 and 41,850,162 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	482,032	480,699
Additional paid-in capital	37,226	17,988
Accumulated other comprehensive loss	(428)	—
Accumulated deficit	(239,313)	(210,266)
TOTAL SHAREHOLDERS' EQUITY	279,517	288,421
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$ 364,075	\$ 368,715

Repare Therapeutics Inc.
Consolidated Statements of Operations
(Unaudited)
(Amounts in thousands of U.S. dollars, except share and per share data)

	Year Ended December 31,	
	2022	2021
Revenue:		
Collaboration agreements	\$ 131,830	\$ 7,600
Operating expenses:		
Research and development, net of tax credits	119,066	90,047
General and administrative	32,560	26,213
Total operating expenses	151,626	116,260
Loss from operations	(19,796)	(108,660)
Other income (expense), net		
Realized and unrealized (loss) gain on foreign exchange	308	(144)
Interest income	5,631	259
Other expense, net	(43)	(41)
Total other income, net	5,896	74
Loss before income taxes	(13,900)	(108,586)
Income tax (expense) benefit	(15,147)	1,678
Net loss	\$ (29,047)	\$ (106,908)
Net loss per share attributable to common shareholders—basic and diluted	\$ (0.69)	\$ (2.83)
Weighted-average common shares outstanding—basic and diluted	41,922,042	37,818,115

	Three Months Ended December 31,	
	2022	2021
Key financial highlights:		
Revenues from collaboration agreements	\$ 18,198	\$ 6,877
Research and development, net of tax credits	\$ 29,891	\$ 27,972
General and administrative	\$ 7,939	\$ 7,639
Net loss	\$ (31,658)	\$ (28,290)
Net loss per share attributable to common shareholders—basic and diluted	\$ (0.75)	\$ (0.70)
Weighted-average common shares outstanding—basic and diluted	41,979,869	40,168,285

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