

Ortho Regenerative Technologies Reports Its Second Quarter 2022 Results

- **Significant progress made towards securing IND approval for our Rotator Cuff repair Phase I/II trial**
- **Type A meeting with FDA scheduled on October 5, 2021**
- **Eight clinical trial sites qualification and scientific training completed**
- **Extension of Convertible Debentures improves working capital by \$1.8 million**
- **Two new U.S. industry veterans join the Board of Directors**

MONTREAL, QC, Sept. 30, 2021 /CNW/ - [Ortho Regenerative Technologies Inc.](#) (CSE: ORTH) (OTCQB: ORTIF) ("**Ortho**" or the "**Company**"), a clinical stage orthobiologics company focused on the development of novel soft tissue repair regenerative technologies, today reported its financial results and highlights for the second quarter of its 2022 fiscal year ended on July 31, 2021.

"Significant progress in addressing the FDA IND clinical hold during the second quarter and up to now was accomplished. In July, the three most complex requests from the FDA were successfully addressed and accepted by the FDA. In early September, we submitted our response to the FDA on the extended clinical hold related to the two remaining issues. We first provided new information related to the elemental impurities testing methods and have accepted the FDA recommendation to use a higher-resolution method for small molecule impurity testing", said Claude LeDuc, President, and CEO of Ortho. "Proactively, the Company scheduled a type A meeting on October 5, 2021, with the FDA, should the FDA still request further clarification on the last issue relating to a elemental impurities testing method."

"Concurrently, the Company continued working on the preparation of the U.S. clinical trial. So far, eight sites have been qualified, with ongoing budget negotiation, and Clinical Review Board (CRB) applications underway. Four other U.S. sites are currently going through the qualification process as we speak to allow for a minimum of 10 sites to participate in our Rotator Cuff Tear repair clinical trial", concluded Mr. LeDuc.

Commenting on the second quarter 2022 results, Luc Mainville, Ortho's Senior Vice-President and Chief Financial Officer, said: "We carefully managed our financial resources during the second quarter. The extension of the convertible debentures has favourably impacted our working capital by removing \$1.8 million worth of short-term maturities and ensures that available cash resources are used to address operating requirements. We look forward to the clearance of our IND by the FDA in the near future and the acceleration of our clinical program activities that will follow".

Second Quarter 2022 ORTHO-R Program Highlights

- In July 2021, the Company provided and filed all requested CMC-related data and characterization information in a formal response to the U.S. Food and Drug Administration (FDA), aiming to address the clinical hold on its Investigational New Drug (IND) application for ORTHO-R.
- In June 2021, the Company received a clinical hold letter from the FDA related to its IND

application to begin a phase I/II clinical trial for ORTHO-R, a drug/biologic combination product candidate used as an adjunct to standard of care surgery in rotator cuff tear repair. The FDA requested additional Chemistry, Manufacturing, and Control ("CMC") related information.

Second Quarter 2022 Corporate Highlights

- In July 2021, the Company announced the voting results from its Annual General and Special Meeting of Shareholders ("AGM") held via videoconference on July 21, 2021. The following nine (9) nominees were elected as Directors of the Company to hold office until the next Annual Meeting of Shareholders or until their successors are elected or appointed: Mr. Michael Atkin, Mr. Pierre Laurin, Mr. Claude LeDuc, Dr. Brent Norton, Mr. Patrick O'Donnell, Mr. Steve Saviuk, Mr. Tom E.S. Wright, Mr. Howard P. Walthall, and Mr. Tim Cunningham. Ernst & Young LLP was appointed as auditor of the Company to hold office until the next Annual Meeting of Shareholders, and the Equity Incentive Plan was approved by a resolution of Disinterested Shareholders.
- In July 2021, the Company amended three series of debentures and warrants to extend their respective maturity dates. The original maturity dates of the 10% unsecured convertible debentures and share purchase warrants of the Company were extended from 24 months after their respective dates of issuance to May 1, 2023. The conversion price of the debentures, the exercise price and other terms of the Warrants remain unchanged.
- In June 2021, the Company appointed Messrs. Howard Walthall and Tim Cunningham to its Board of Directors. Concurrent with their appointments, each of them received 100,000 incentive share options at an exercise price of \$0.36 per share and expiring June 15, 2029. Mr. Walthall is a seasoned life sciences executive whose multi-faceted experience includes cellular biologics, tissue engineering, medical devices, and allografts. He has an extensive background in regenerative medicine, orthopedics and advanced wound care. Mr. Cunningham brings over 30 years of extensive finance and operations leadership experience in the biotechnology and software industries to his work with his public and private Danforth clients, as a CFO with a demonstrated record of success in building startup enterprises into industry leaders and scaling larger entities globally.
- In June 2021, Mukesh Ahuja, the Company's Vice-President Clinical and Medical Affairs transitioned into a consultant role while assuming the same functions for the Company.

Second Quarter 2022 Subsequent Events

- On September 21, 2021, the Corporation extended its Research and Collaborative Agreement with Ecole Polytechnique until May 2022. The extension will ensure continued support from the Polytechnique staff and continued access to their laboratories required to successfully develop the Corporation's various R&D projects leveraging the Corporation's proprietary biopolymer, such as ORTHO-R for rotator cuff repair, ORTHO-M for Meniscus repair, and others.
- On September 2, 2021, the Company worked with its U.S. CMC testing experts on the new FDA requests and responded to the Second Clinical Hold letter by submitting additional clarification on elemental impurities identification and quantification testing methods to the FDA. The Company is confident that its response to the Second Clinical Hold letter will address both the requirements for clarifications and address the deficiencies to the complete and final satisfaction of the FDA. The Company requested a type A meeting with the FDA, should the FDA still request further clarification on the proposed elemental impurities testing method. The type A meeting has been scheduled for October 5, 2021.
- On August 17, 2021, The Company received, a "Second Clinical Hold" letter from the FDA. In

our July response, the three most complex addressed issues were accepted by the FDA. The second FDA Clinical Hold letter referred to further clarification on CMC Elemental impurity testing method and a request to use a different testing method for small molecule impurity testing.

Financial Statements and MD&A

Ortho's financial statements and Management's Discussion and Analysis for the three-month and six-month periods ended July 31, 2021, are available on SEDAR at www.sedar.com.

About Ortho Regenerative Technologies Inc.


Ortho is a clinical stage orthobiologics company dedicated to the development of novel therapeutic soft tissue repair technologies to dramatically improve the success rate of orthopedic and sports medicine surgeries. Our proprietary RESTORE technology platform is a proprietary muco-adhesive Chitosan-based biopolymer matrix, specifically designed to deliver biologics such as Platelet-Rich Plasma (PRP) or Bone Marrow Aspirate Concentrate (BMAC), to augment and guide the regeneration of new tissue in various musculoskeletal conditions. ORTHO-R, our lead Chitosan-PRP hybrid drug/biologic implant combination product, is formulated and designed to increase the healing rates of occupational and sports-related injuries to tendons, meniscus and ligaments. Other formulations are being developed for cartilage repair, bone void filling and osteoarthritis treatment. The proprietary Chitosan-PRP combination ORTHO-R implant can be directly applied into the site of injury by a surgeon during a routine operative procedure without significantly extending the time of the surgery and without further intervention. Considering the significant potential of our technology platform, Ortho continues to assess new therapeutic target uses outside of the soft tissue repair field. Further information about Ortho is available on the Company's website at www.orthorti.com and on SEDAR at www.sedar.com. Follow us on LinkedIn and Twitter.

Forward-Looking Statements

This news release may contain certain forward-looking statements regarding the Company's expectations for future events. Such expectations are based on certain assumptions that are founded on currently available information. If these assumptions prove incorrect, actual results may differ materially from those contemplated by the forward-looking statements contained in this press release. Factors that could cause actual results to differ include, amongst others, uncertainty as to the final result and other risks. The Company disclaims any intention or obligation to publicly update or revise any forward- looking statements, whether as a result of new information, future events or otherwise, other than as required by security laws.

NEITHER THE CANADIAN SECURITIES EXCHANGE NOR ITS REGULATIONS SERVICES PROVIDER HAVE REVIEWED OR ACCEPT RESPONSIBILITY FOR THE ADEQUACY OR ACCURACY OF THIS RELEASE.

SOURCE Ortho Regenerative Technologies Inc.

 View original content to download multimedia:

<http://www.newswire.ca/en/releases/archive/September2021/30/c6085.html>

%SEDAR: 00037950E

For further information: Claude LeDuc, President and Chief Executive Officer, (514) 693-8804, leduc@orthorti.com or Luc Mainville, Senior Vice-President and Chief Financial Officer, 514-693-8854, mainville@orthorti.com or Frederic Dumais, Director Communications and Investor Relations, (514) 782-8803, dumais@orthorti.com

CO: Ortho Regenerative Technologies Inc.

CNW 17:28e 30-SEP-21