# ORTHO REGENERATIVE TECHNOLOGIES REPORTS ITS THIRD QUARTER 2022 RESULTS

- **FDA clears Investigational New Drug application for the ORTHO-R rotator cuff tear repair U.S. Phase I/II clinical trial**
- **$1.05 million non-brokered private placement closed**

MONTREAL, Dec. 21, 2021 /CNW Telbec/ - **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 third quarter of its 2022 fiscal year ended on October 31, 2021.

"Our sustained efforts to resolve the FDA clinical hold during the third quarter were rewarded with the FDA granting Ortho its first Investigational New Drug Application ("IND") for its lead program, ORTHO-R for rotator cuff tear repair. The recent lift of the clinical hold allows us to advance swiftly with our Phase I/II U.S. clinical trial and marks the beginning of a new era for Ortho," said Claude LeDuc, President and CEO." We are now hard at work proceeding with getting all chosen clinical centers across the U.S. to initiate patient recruitment. This will take place after Institutional Review Board filings and other required preparation work are completed. We are expecting our first patients to be enrolled during the first quarter of calendar 2022. We are proud to have reached this pivotal milestone with ORTHO-R, our lead Drug/Biologics combination product. We look forward to demonstrating in patients the unique properties of our proprietary technology, aiming at accelerating tissue repair, and therefore improving the success rate of the standard of care surgery in rotator cuff repair."

Commenting on the third quarter 2022 results, Luc Mainville, Ortho's Senior Vice-President and Chief Financial Officer, said: "The sound management of our liquidities during the third quarter combined to the proceeds from the recent closing of a $1.05 million private placement allows us to officially get the Phase I/II U.S. clinical trial underway. We will continue to carefully allocate our financial resources to ensure we maintain our clinical development program and other key activities on track."

### Third Quarter 2022 ORTHO-R Program Highlights

- On October 4, 2021, the Company held a successful Type A meeting with the FDA following the receipt of a letter on October 1, 2021, related to two pending CMC elements for which more information was required. The FDA cleared the small-molecule impurity testing issue and requested the use of standard reference material and provided a list of certified standards to consider with regards to the elemental impurity testing.
- 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's response to the Second Clinical Hold letter addressed both the requirements for clarifications and deficiencies. The Company requested a type A meeting with the FDA.
- 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.

## Third Quarter 2022 Corporate Highlights

- 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 Corporations' 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.

## Third Quarter 2022 Subsequent Events

- On December 13, 2021, the Company announced that the clinical hold on its U.S. Investigational New Drug ("IND") application had been lifted by the U.S. Food and Drug Administration ("FDA") and that the Company was cleared to proceed with its Phase I/II U.S clinical trial to evaluate the safety and efficacy of ORTHO-R as an adjunct treatment to standard of care surgery in rotator cuff tear repair. By lifting the clinical hold, the FDA confirmed that Ortho had satisfactorily addressed all issues related to the August 17, 2021, clinical hold letter.
- On December 13, 2021, the Company closed a non-brokered $1.05 million private placement offering (the "Private Placement") of unsecured convertible note units (the "Note Units"), with $380,250 of Insiders' subscriptions. The Company issued 1,075 Note Units at a price of $975 per Note Unit for total gross proceeds of $1,048,125. Each Note Unit consisted of one (1) unsecured convertible note of the Company in the principal amount of $1,000 (each a "Note") and 1,000 Class "A" share purchase warrants (each a "Warrant"). The Notes bear interest at a rate of 10% per annum from the date of issue, payable in cash, semi-annually in arrears and will mature (the "Maturity Date") on the earlier of (i) 12 months following the closing date of the Private Placement, or (ii) 20 days following the closing of a capital raise in the form of an equity or debt financing of at least $5 Million (the "Capital Raise"). Any unpaid interest payments will accrue and be added to the principal amount of the Notes. Should the Company complete a Capital Raise prior to the Maturity Date, the holder of a Note will have the option, but not the obligation, to convert the outstanding value of the Note and any accrued and unpaid Interest thereon, into the equity securities and/or debt instrument to be issued pursuant to the Capital Raise, at the same terms and conditions. Each Warrant will entitle the holder thereof to purchase one Class A Share (each, a "Share") at an exercise price of $0.50 at any time up to 24 months following December 13, 2021. The Notes and the Warrants are subject to a statutory hold period under the applicable securities laws and in such case the certificates evidencing the Notes and the Warrants will bear a legend to that effect, as applicable. The Company has paid $21,084 in commissions and issued 21,625 finders' warrants in connection with the Private placement, in compliance with applicable securities laws. The net proceeds from the Private placement will be used to 1) Initiate the ORTHO-R Phase I/II US Clinical trial for Rotator cuff tear repair, and 2) For working capital and general corporate purposes.
- On November 12, 2021, the Company filed its response with the FDA comprised of the remaining information and data requested during the October 4th, 2021, FDA Type A meeting.

## Third Quarter 2022 Financial Statements and MD&A

Ortho's financial statements and Management's Discussion and Analysis for the three-month and nine-month periods ended October 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. Also 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.



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