



## **PRESS RELEASE**

### **FOR IMMEDIATE DISCLOSURE**

#### **ORTHO REGENERATIVE TECHNOLOGIES REPORTS ITS FOURTH QUARTER AND 2022 YEAR-END RESULTS**

- **Phase I/II clinical trial IND application cleared by FDA for testing ORTHO-R in combination with PRP for rotator cuff tear repair**
- **ORTHO-R / PRP combination becomes the first drug/biologic implant combination product cleared by the FDA for clinical trial testing**
- **Philippe Deschamps appointed as new CEO in March 2022**
- **Signing of Material Transfer Agreement with global strategic medical company**
- **Key U.S., Canadian and European composition and method patent secured for ORTHO-R / PRP soft tissue repair platform, protecting core IP until 2035**
- **\$3.2 Million over-subscribed private placement secured in Q1-2023**

Montreal, QC, May 20, 2022 – **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 fourth quarter and fiscal year ended January 31, 2022.

“Securing the IND clearance for initiating our Phase I/II rotator cuff tear repair clinical trial, was truly our biggest accomplishment in fiscal year 2022”, said Philippe Deschamps, President, and CEO. “Following FDA’s new requirement to obtain a biologics licence for regenerative treatments, we are now leading the way with our proprietary Ortho-R biopolymer PRP combination, being tested in human for improving standard of care surgeries. With 6 US sites now fully contracted and 3 sites actively screening patients, enrollment of our first patients is imminent”.

Commenting on the fourth quarter and year-end 2022 results, Luc Mainville, Ortho’s Senior Vice-President, and Chief Financial Officer, said; “During Fiscal Year 2022, we remained disciplined with the use of our financial resources while addressing the FDA requirements related to our Ortho-R / PRP Phase I/II IND filing. Several operational milestones have been accomplished during the past year while successfully addressing

the FDA's clinical hold, including the production of our cGMP clinical trial material, successful prosecution of our key patents in the US, Canada and Europe, the qualification, and negotiations with our 10 U.S. clinical sites. With the recent closing of our oversubscribed \$3.2 million private placement, Ortho is now well positioned to accelerate Phase I/II clinical trial activities and solidify its position as the leading player in the dynamic regenerative medicine market".

#### **Fourth Quarter and Year-End 2022 ORTHO-R Program Highlights**

- In December 2021, the Company was cleared by the U.S. Food and Drug Administration ("FDA") to proceed with its Phase I/II U.S clinical trial to evaluate the safety and efficacy of ORTHO-R in combination with PRP as an adjunct treatment to standard of care surgery in rotator cuff tear repair following the lift of the clinical hold;
- In June 2021, the Company received a clinical hold letter from the U.S. Food and Drug Administration ("FDA") related to its Investigational New Drug (IND) application to begin a Phase I/II clinical trial with ORTHO-R / PRP; and
- In April 2021, the Company submitted an IND application to the U.S. Food and Drug Administration for the initiation of a Phase I/II clinical trial with ORTHO-R / PRP for rotator cuff tear repair.

#### **Fourth Quarter and Year-End 2022 Corporate Highlights**

- In December 2021, the Company closed a non-brokered \$1.05 million private placement offering of unsecured convertible note units, with \$380,250 of Insiders' subscriptions and issued 1,075 Note Units at a price of \$975 per Note Unit;
- In July 2021, the Company amended three series of debentures and warrants to extend their respective maturity dates 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;
- In April 2021, the Company secured a \$150,000 government grant to support ongoing ORTHO-R research over the next 2 years;
- In March 2021, the Company announced that its common shares were eligible for electronic clearing and settlement through the Depository Trust Company ("DTC") in the United States; and

- In February 2021, the Company appointed Patrick O'Donnell to its Board of Directors and announced the retirement of Prof. Michael Buschmann and Prof. Caroline Hoemann from its Board of Directors.

#### **Fourth Quarter and Year-End 2022 Subsequent Events**

- In May 2022, the Company issued 500,000 warrants with an exercise price of \$0.35 per Common Share and expiring April 30, 2023 as compensation to non-related parties providing social media support and other corporate services;
- In May 2022, the Company received a key U.S., Canadian and European composition and method patent from the U.S. Patent and Trademark Office for its ORTHO-R soft tissue repair platform protecting its core IP until 2035;
- In April 2022, the Company closed an oversubscribed non-brokered private placement and issued 16,000,000 Units at a price of \$0.20 per Unit for total gross proceeds of \$3.2 million with approximately \$560,000 of Insiders' subscriptions. Each Unit consisted of one (1) Class A share of the Company and one Common share purchase warrant exercisable into one (1) Share in the capital of the Company at the price of \$0.35 per Warrant Share for a period of 24 months from closing;
- In April 2022, the Company granted 2,000,000 share purchase options (the "Options") and 551,938 Restricted Share Units ("RSU") to its CEO, Philippe Deschamps. 50% of the Options and RSU's will vest annually and equally over the first 3 years following the Date of Grant. The balance of the Options and RSU's will vest based on achievements of predetermined operational and corporate milestones;
- In March 2022, the Company appointed Philippe Deschamps as its new Chief Executive Officer following the retirement of Mr. LeDuc; and
- In February 2022, the Company entered into a Material Transfer Agreement with an undisclosed, industry-leading, global strategic medical company for the exclusive use of their proprietary platelet-rich plasma system in its ORTHO-R rotator cuff tear repair, phase I/II U.S. clinical trial.

#### **Fourth Quarter and Year-End 2022 Financial Statements and MD&A**

Ortho's financial statements and Management's Discussion and Analysis for the three-month and year-end periods ended January 31, 2022, are available on SEDAR at [www.sedar.com](http://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 tendinopathies, 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](http://www.orthorti.com) and on SEDAR at [www.sedar.com](http://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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