



PRESS RELEASE

FOR IMMEDIATE DISCLOSURE

ORTHO REGENERATIVE TECHNOLOGIES REPORTS ITS FIRST QUARTER 2022 RESULTS

- **Submission of first Investigational New Drug (“IND”) application to the US FDA for the initiation of a phase I/II clinical trial for testing ORTHO-R for rotator cuff tear repair**
- **DTC eligibility secured in the U.S. for the Company’s common shares**
- **Addition of three U.S. industry veterans to its Board of Directors**
- **\$150,000 government grant received to support ORTHO-R research**

Montreal, QC, June 29, 2021 – [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 first quarter of its 2022 fiscal year ended on April 30, 2021.

“The filing of our IND with the FDA for our U.S. based Phase I / II clinical trial for testing ORTHO-R for rotator cuff tear repair was achieved in the first quarter. Following receipt of a clinical hold letter from the FDA on June 4, 2021, we are currently addressing the supplemental information requested by the FDA and anticipate submitting our formal response shortly. The FDA is then expected to respond to our supplemental IND information within the following 30 days.”, said Claude LeDuc, President and CEO of Ortho. “While waiting for our IND clearance, we continue progressing on our Phase I/II clinical trial preparation activities to ensure minimal impact on the overall timeline for executing the Phase I/II trial. Assuming clearance of our IND application by the FDA later this summer and based on the quality and number of US clinical centers who have indicated their interest in participating in the Ortho-R trial, we are optimistic in being able to complete our Phase I/II clinical trial enrollment activities without materially impacting our timelines.”

Commenting on the first quarter 2022 results, Luc Mainville, Ortho's Senior Vice-President and Chief Financial Officer, said: "We continue to commit most of our financial resources toward our ORTHO-R clinical program. Following successful financings completed last year, we have significantly improved our cash position compared to the first quarter 2021. This has enabled us to continue advancing our lead program and will help fund further progress expected over the coming quarters.

First Quarter 2022 ORTHO-R Program Highlights

- 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 of ORTHO-R in rotator cuff tear repair.

First Quarter 2022 Corporate Highlights

- Cash position has increased from \$54,000 at the end of Q1-21 to \$1,613,000 as at the end of Q1-22;
- 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. DTC is a subsidiary of the Depository Trust & Clearing Corporation, a U.S. company that manages the electronic clearing and settlement of publicly traded companies;
- 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. Patrick O'Donnell is the President and Chief Executive Officer of HD LifeSciences, a prominent life sciences executive with over 25 years of experience guiding companies in both the pre-commercial and commercial stages. Mr. O'Donnell brings a comprehensive understanding of the medical device, orthobiologics and biomaterial industries in the orthopedic, spine, neurosurgery, and sports medicine markets;
- In February 2021, the Company retained Westwicke, an ICR company, as its investor relations advisors for the U.S. markets; and
- In April 2021, the Company secured a \$150,000 government grant to support ongoing ORTHO-R research over the next 2 years.

First Quarter 2022 Subsequent Events

- 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;
- 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. Vesting of the options will take place as per the Company's plan. 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 and has overseen multiple highly successful product development projects and new product launches. 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; and
- 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 application to begin a phase I/II clinical trial for ORTHO-R, its 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 related information.

Financial Statements and MD&A

Ortho's financial statements and Management's Discussion and Analysis for the three-month period ended April 30, 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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