

Ortho Regenerative Technologies Reports Its Fourth Quarter and 2021 Year-End Results

- **\$6.7 million raised from non-brokered private placements with insider's participation totaling \$1.1 million**
- **ORTHO-R designated as a Drug/Biologic combination product by the FDA**
- **Submission of first IND to the US FDA for the initiation of a phase I/II clinical trial testing ORTHO-R for rotator cuff tear repair**
- **Positive pivotal preclinical study results confirmed, safety profile of ORTHO-R and statistically significant superiority over standard of care surgery for rotator cuff tear repair**
- **Entered into Global licensing agreement to use, manufacture, sublicense and sell PRP fractional system in combination with ORTHO-R**
- **Listing of our shares on the US OTCQB market under the "ORTIF" symbol**

MONTREAL, June 1, 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 fourth quarter and fiscal year ended January 31, 2021.

"2021 was marked by the achievement of a series of material corporate milestones. We completed our GLP pivotal preclinical study in rotator cuff tear repair, confirming the safety profile and superiority of ORTHO-R used as an adjunct to Standard of Care ("SOC") surgery over SOC surgery alone in rotator cuff tear repair. ORTHO-R was designated by the FDA, as a Drug/Biologic combination product which has significantly increased the commercial value of our platform and products. We also secured a global exclusive licensing agreement with Hanuman Pelican, for the use, manufacture, sublicense, and selling of the Buoy Suspension Fractional System, one of the top PRP system on the market, to be used in combination with ORTHO-R in various soft tissue repair conditions, validating the attractiveness of our technological platform. Finally, during FY-2021 hard work from the Ortho Team and its CROs and CMC partners have advanced our lead program toward its clinical trial phases, resulting in April 2021 with the filing of our first IND with the US FDA", said Claude LeDuc, President and CEO of Ortho . "We expect 2022 to be a pivotal year for Ortho as we await clearance of our IND by the FDA to start enrolling patients in our first U.S. based rotator cuff tear repair phase I / II clinical trial. We are ready to proceed and look forward to the opportunity of demonstrating how our platform can help improve the success rate of orthopedic and sports medicine soft tissue repair surgeries".

Commenting on the fourth quarter and 2021 year-end results, Luc Mainville, Ortho's Senior Vice-President and Chief Financial Officer, said: "We have significantly strengthened our balance sheet over the last fiscal year with a total of \$6.7 million raised from three (3) non-brokered private placements, including a significant contribution from insiders. We have also taken steps to increase liquidity for our shares by securing a US OTCQB listing and facilitating access for US investors".

2021 ORTHO-R Program Highlights

- In August 2020, the Company announced that ORTHO-R was designated as a Drug/Biologic combination product, by the FDA Office for Combination Products. The jurisdictional assignment for ORTHO-R will be the Center for Biologics Evaluation and Research (CBER);
- In July 2020, the Company announced new 6-month positive results following completion of its

pivotal preclinical study report in Rotator Cuff Tear (RCT) repair under Good Laboratory Practices (GLP) conditions. The study compared Standard of Care (SOC) surgery augmented with Ortho-R 2mL or Ortho-R 3mL (Chitosan-PRP) treatment groups, versus SOC alone as a control. The new results from the completion of the statistical analysis of the histological data performed respectively by independent biostatisticians and licensed veterinarian pathologists blinded to treatment groups, confirmed evidence of better tendon and insertion site histology and overall repair in RCT treated with ORTHO-R; and

- In March 2020, the Company reported MRI 3-month positive results following completion of its pivotal preclinical study in Rotator Cuff Tear repair. The results confirmed the safety profile of ORTHO-R as well as statistical significance over standard-of-care. Standard of care surgery (anchors + sutures) was compared to standard of care surgery plus ORTHO-R, the Company's proprietary muco-adhesive orthobiologics hybrid implant. Both the pilot and pivotal studies demonstrated a decrease in tendon gap at 3 months in the ORTHO-R treated groups compared to the standard of care control groups. A decreased tendon gap is indicative of faster restoration of tissue structure, observed by a more normal MRI signature.

2021 Financial Highlights

- In December 2020, the Company completed a non-brokered private placement of secured non-convertible debenture units for gross proceeds of \$3.0 million. The Company issued 3,000 secured non-convertible debenture units at a price of \$1,000 per Debenture Unit for total gross proceeds of \$3.0 million. Each Debenture Unit consisted of one 3-year, 10% secured non-convertible debenture of the Company in the principal amount of \$1,000 and 500 Class "A" share purchase warrants. Each Warrant will entitle the holder thereof to purchase one Class "A" of the Company at an exercise price of \$0.75 at any time up to 36 months following the closing date of the Offering. The net proceeds from the Offering will be used to fund the following ongoing value creation activities: 1) U.S. IND regulatory submission to secure FDA's approval to start our Phase I/II US clinical trial on ORTHO-R for rotator cuff tear repair 2) Clinical sites qualification and management 3) Clinical study institutional and Ethical Review Boards approval and administration 4) Clinical sites training 5) Initiating patient enrolment in clinical trial 6) General and administrative corporate purposes;
- In October 2020, the Company's shares started trading on the OTCQB market in the United States under the symbol "ORTIF". The Company has maintained the listing of its Shares on the CSE under the symbol "ORTH";
- In September 2020, the Company completed a \$137,600 additional non-brokered private placement of units. The additional Private Placement was conducted at the same terms and followed the closing of a non-brokered and oversubscribed \$2.5 million private placement of units completed on August 21, 2020 bringing the overall gross proceeds raised through the two private placements to \$2.6 million;
- In August 2020, the Company closed a non-brokered \$2.5 million private placement of units. The Company issued 7,733,812 units at a purchase price of \$0.32 per Unit for total gross proceeds of \$2,474,820. Each Unit consisted of one (1) class A share of the Company and one (1) Share purchase warrant of the Company. Each Warrant is exercisable into one (1) Share in the capital of the Company at the price of \$0.50 per Warrant Share for a period of 36 months from closing. The net proceeds of the Offering will be used to fund the following ongoing value creation activities: 1) Securing FDA's approval to start our US clinical trial on ORTHO-R for rotator cuff tear repair 2) Manufacturing GMP Clinical Trial batch for ORTHO-R 3) Completing US clinical trial investigation sites selection, setting, and training 4) Starting US clinical trial patients enrolment activities 5) Secure US exchange listing for Ortho's shares 6) General and administrative corporate purposes; and
- In April 2020, the Company closed a non-brokered \$1.1 million private placement of convertible debenture units. The Company issued 1,060 unsecured convertible debenture units (the "Units") at a purchase price of \$1,000 per Unit for total gross proceeds of \$1,060,000. Each Unit consists of one 10% unsecured convertible debenture in the principal amount of \$1,000

convertible at a \$0.30 price per Class "A" share of the Company and 2,000 Class "A" share purchase warrants, expiring 24 months after the date of issuance of such Warrants. Each Warrant will entitle the holder thereof to purchase one Common Share at an exercise price of \$0.50. The net proceeds from the Private Placement will be used to strengthen the Company's working capital position and cover some of the costs related to the following ORTHO-R programs: 1) pre-clinical pivotal study final report 2) ongoing FDA regulatory activities and 3) ongoing US clinical trial preparedness work.

2021 Corporate Highlights

- In January 2021, the Company entered into a global licensing agreement with Hanuman Pelican Inc. for the use of the Buoy Suspension Fractional System in combination with ORTHO-R, Ortho's lead Chitosan PRP hybrid drug/biologic implant combination product. The Agreement grants Ortho an exclusive global license (excluding Japan) to use, manufacture, sublicense and sell the Buoy Suspension Fractional System in combination with ORTHO-R in the following fields: 1) Tendons, 2) Ligaments, 3) Meniscus, 4) Cartilage, and 5) Wound Healing (non-exclusive);
- In October 2020, the Company appointed Mukesh Ahuja as its new Vice-President Clinical and Medical Affairs. Mukesh Ahuja, MBBS, MSc is a highly qualified, medical executive with fourteen years of US experience as a clinical expert in Orthopedics, managing dozens of orthopedic clinical studies and partnering with surgeons to advance novel research approaches. Prior to joining Ortho Dr. Ahuja worked at Orthofix Medical, Inc. where he was responsible for the motion preservation program of the spine business franchise. Prior to Orthofix, Dr. Ahuja was the Director of Medical and Clinical Affairs for Medacta USA, Inc. Dr. Ahuja holds a Masters of Science in Clinical Research from Rush University Medical Center, Chicago, completed a Health Care Management Executive Certificate Program from Loyola University, Chicago, achieved his Certified Principal Investigator (CPI®) certification from ACRP and received a Bachelor of Medicine and Bachelor of Surgery (MBBS) medical degree from Liaquat University of Medical & Health Sciences, Pakistan and a Bachelor of Arts – Political Science and History, University of Sindh, Pakistan;
- In June 2020, the Company appointed Mr. Michael Atkin as its new independent Chairman of the Board. Mr. Atkin has over 30 years of experience in the life sciences sector. Mr. Atkin is President of Syzent Partners Ltd. He holds an MBA from Columbia University's graduate school of business (New York, USA) and a BA from the University of Kent at Canterbury (Great Britain); and
- In May 2020, the Company entered into a strategic and licensing agreement with Ingenew Pharmaceuticals Inc. The Agreement will explore the expansion of the scope of Ortho's proprietary technological platform applications to include the delivery of therapeutics.

Subsequent Events

- In April 2021, the Company announced it had submitted an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for the initiation of a Phase I/II clinical trial of ORTHO-R in rotator cuff tear repair;
- 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 for the trading of its shares on the US OTCQB market.;
- In February 2021, the Company announced the appointment of Patrick O'Donnell to its Board of Directors and 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; and
- In February 2021, the Company retained Westwicke, an ICR company, as its investor relations

advisors for the U.S. markets.

Financial Statements and MD&A

Ortho's financial statements and Management's Discussion and Analysis for the three-month and fiscal year ended January 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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