

Ortho Regenerative Technologies Announces Filing of Response to Type A Meeting with FDA and Non-Brokered \$1.5 Million Private Placement

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- **Filing of response to Type A meeting addresses remaining information and data requested by FDA**
- **Insiders to lead Private Placement with subscriptions totaling more than \$400,000**
- **Net proceeds to be used to initiate ORTHO-R Phase I/II U.S. clinical trial for rotator cuff tear repair**

MONTREAL, Nov. 12, 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 announced that it has filed its response with the FDA comprised of the remaining information and data requested during the October 4th, 2021 FDA Type A meeting. IND clearance for the ORTHO-R Phase I/II Clinical trial is now expected within 30 days. The Company also announces a non-brokered private placement offering (the "**Private Placement**") of up to CAD \$1,500,000 in unsecured convertible note units (the "**Note Units**"), with more than \$400,000 of Insiders' subscriptions already secured.

Ortho-R US IND update

The Company confirms that it has filed the reports requested by the FDA related to CMC elemental and small molecule impurity testing and is now awaiting clearance of the clinical hold within 30 days of this submission.

Immediately after IND clearance, IRB sites approval, and finalization of initial clinical trial agreements by site the company will start patient enrolment, in a Phase I/II prospective, randomized, controlled, and blinded clinical trial, to evaluate the safety and efficacy of ORTHO-R as an adjunct to standard of care surgery vs standard of care surgery alone in rotator cuff tear repair. The clinical trial will enroll a total of 78 patients at ten clinical sites throughout the U.S.

\$1.5 Million Private Placement

Each Note Unit will consist of one (1) unsecured convertible note in the principal amount of \$1,000 (each a "**Note**") and 500 Class A share purchase warrants (each a "**Warrant**").

The Notes will bear interest at a rate of 10% per annum from the date of issue, payable in cash, semi-annually in arrears and will mature on the earlier of 12 months following the closing date of the Private Placement, or 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. In addition, a set-up fee equivalent to 2% of each respective participation shall be paid in cash on closing.

The holder of each 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 \$0.75 at any time up to 24 months following the closing date of the Private Placement (the "**Closing Date**").

The Private Placement is non-brokered; however the Company will pay finder's fees equal to **2 %** of the gross proceeds raised from Accredited Investors introduced to the Company by finders, payable in cash, plus 2% compensation warrants (to be calculated as a % of the numbers of Warrants issued).

Net proceeds of 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.

The Notes and the Warrants will be 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.

Closing of the Private Placement is expected to occur on or about November 30, 2021, but no later than the date of granting of the IND by the FDA, and is subject to certain conditions, including but not limited to, the receipt of all necessary regulatory and stock exchange approvals, including the approval of the CSE.

The Note Units will be offered and sold by private placement (i) in Canada to "accredited investors" within the meaning of *Regulation 45-106 respecting Prospectus Exemptions* and other exempt purchasers in each province of Canada (ii) in the United States on a private placement basis only under Regulation D, Rule 144A or other available U.S. registration exemptions and (iii) jurisdictions outside of Canada and the United States, in each case in accordance with all applicable laws provided that no prospectus, registration statement or similar document is required to be filed in such jurisdiction and the Company does not thereafter become subject to continuous disclosure obligations in such jurisdictions.

This press release does not constitute an offer to sell or a solicitation of an offer to buy securities in the United States. The securities referenced herein have not been and will not be registered under the United States Securities Act of 1933, as amended (the "U.S. Securities Act"), or any state securities laws and may not be offered or sold in the United States except in compliance with one or more exemptions from the registration requirements of the U.S. Securities Act and applicable securities laws

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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For further information: Company, Claude LeDuc, President and Chief Executive Officer, (514) 651-1282, leduc@orthorti.com; Investors, Frederic Dumais, Director Communications and Investor Relations, (514) 782-8803, dumais@orthorti.com

CO: Ortho Regenerative Technologies Inc.

CNW 07:00e 12-NOV-21