

# Ortho Regenerative Technologies Reports its Fourth Quarter and 2020 Year-End Results

- \$3.2 million raised from non-brokered private placements with insider's participation totaling \$2.2 million
- Positive pivotal preclinical study results confirmed safety profile of ORTHO-R and statistical significance over standard-of-care
- Strategic licensing agreement signed to expand scope of proprietary technological platform applications to include delivery of therapeutics

MONTREAL, May 29, 2020 /CNW/ - Ortho Regenerative Technologies Inc. (CSE: ORTH) ("Ortho RTI" or the "Company"), an emerging orthobiologics company, today reported its financial results and highlights for the fourth quarter and fiscal year ended January 31, 2020.

"Our 2020 fiscal year was marked by significant progress in advancing all aspects of our Ortho-R lead program towards the clinical phase. We successfully completed our pivotal preclinical study in Rotator Cuff Tear repair which confirmed Ortho-R's safety profile and statistical significance over standard-of-care. We have refined the regulatory pathway to explore advantageous solutions to advance our program into clinical trial stages and are actively pursuing numerous business development discussions and opportunities with various partners", said Claude LeDuc, President and CEO of Ortho RTI. "We look to the 2021 fiscal year with confidence and believe to be well positioned to continue delivering on the expected clinical and corporate milestones".

Commenting on the fourth quarter and 2020 year-end results, Luc Mainville, Ortho RTI's Senior Vice-President and Chief Financial Officer, said: "The significant contribution from insiders and new shareholders has allowed the company to continue progressing during the year. This support is a clear endorsement of the inherent potential of our development programs and other fast-developing corporate initiatives".

### 2020 Ortho-R Program Highlights

- In October 2019, the Company started the histopathology evaluation of the samples collected from the pivotal preclinical trial and successfully completed the manufacturing's methods and process validations. The Company also continued ongoing scale-up and stability activities for the manufacturing of cGMP grade clinical testing material;
- In September 2019, the Company selected MCRA, LLC as its US based orthopedic specialty clinical research organization, to conduct its upcoming rotator cuff tear repair Ortho-R human trial:
- In August 2019, the Company entered into a collaborative Material Transfer Agreement with a leading global orthopaedic Company for the evaluation of a formulation of the Partner's commercial product for its properties when used in conjunction with Ortho's Ortho-R product; and
- In February 2019, the Company initiated a 6-month pivotal animal study on Ortho-R for rotator cuff repair and held a pre-IND (Investigational New Drug) meeting with the FDA to formalize the requirements for the filing of its application to commence human trials on Ortho-R.

## 2020 Financial and Other Corporate Highlights

Between October and December 2019, the Corporation closed two consecutive non-brokered

private placements of convertible debenture units (the "Private Placements"). The Private Placements included \$1,250,000 of new subscriptions and \$894,000 from conversion of loans from Manitex Capital Inc. Insider contribution into the Private Placements totaled \$1,7 million. The Company issued a total of 2,144 unsecured convertible debenture units at a purchase price of \$1,000 per Unit for gross proceeds of \$2,144,000. Each Unit consisted of one 10% unsecured convertible debenture for a principal amount of \$1,000 convertible at a \$0.30 price per Class "A" share and 2,000 Common Share purchase warrants with an exercise price of \$0.50 representing a 60% warrant coverage. Both the Debentures and the Warrants have a maturity date which is 24-month following each respective closing. In the event that the volume weighted average price of the Company's shares over any 20 consecutive trading days is greater or equal to \$1.00, the Corporation may give notice that the Warrant maturity will be accelerated. In such case, the Warrant maturity date will be set 30 days following such notice;

• In June 2019, the Company appointed Messrs. Pierre Laurin and Claude LeDuc to its Board of Directors and nominated Claude LeDuc as its new President and CEO.

### **Subsequent Events**

- In May 2020, the Company entered into a strategic and licensing agreement with Ingenew Pharmaceuticals Inc. to explore the expansion of the scope of Ortho's proprietary technological platform applications to include the delivery of therapeutics;
- In April 2020, the Company closed a non-brokered private placement of convertible debenture units (the "Units"). The Company issued 1,060 Units at a purchase price of \$1,000 per Unit for total gross proceeds of \$1,060,000. Each Unit consisted of one 10% unsecured convertible debenture in the principal amount of \$1,000 (each, a "Debenture") convertible at a \$0.30 price per Class "A" share of the Company ("Common Shares") and 2,000 Class "A" share purchase warrants (each, a "Warrant"), 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. Both the Debentures and the Warrants have a maturity date of April 22, 2022. In the event that the volume weighted average price of the Company's shares over any 20 consecutive trading days is greater or equal to \$1.00, the Corporation may give notice that the Warrant maturity will be accelerated. In such case, the Warrant maturity date will be set 30 days following such notice. The Chief Executive Officer, the Senior Vice-President and Chief Financial Officer, one Director and two senior staff members all participated in the Private Placement for an aggregate amount of \$400,000. Total contribution from insiders in the last three private placements amounts to \$2.1 million representing 66% of the Private Placements; and
- In March 2020, the Company announced 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.

#### Financial Statements and MD&A

Ortho RTI's financial statements and Management's Discussion and Analysis for the three-month and fiscal year ended January 31, 2020 are available on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

## About Ortho Regenerative Technologies Inc.

Ortho RTI is an emerging 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 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 biologic implant 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 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. An Ortho-R Rotator Cuff Tear Repair US clinical trial is being prepared and coordinated. Parallelly, a Pre- Request for Designation has been submitted to the FDA in March 2020, to explore the feasibility to obtain a Device designation regulatory path versus a Biologics designation regulatory path. We are expecting a response in June 2020 and an IDE or IND FDA submission planned during summer 2020. Considering the significant potential of our technology platform, Ortho RTI continues to assess new therapeutic target uses outside of the soft tissue repair field. Further information about Ortho RTI is available on the Company's website at <a href="https://www.orthorti.com">www.orthorti.com</a> and on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>. 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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