

## FORM 7

### August 2021 - MONTHLY PROGRESS REPORT

Name of Listed Issuer: **Ortho Regenerative Technologies Inc. (the “Company” or the “Issuer”)**

Trading Symbol: **ORTH**

Number of Outstanding Listed Securities: **34 914 241**

Date: **September 7<sup>th</sup>, 2021**

This Monthly Progress Report must be posted before the opening of trading on the fifth trading day of each month. This report is not intended to replace the Issuer’s obligation to separately report material information forthwith upon the information becoming known to management or to post the forms required by Exchange Policies. If material information became known and was reported during the preceding month to which this report relates, this report should refer to the material information, the news release date and the posting date on the Exchange website.

This report is intended to keep investors and the market informed of the Issuer’s ongoing business and management activities that occurred during the preceding month. Do not discuss goals or future plans unless they have crystallized to the point that they are "material information" as defined in the Policies. The discussion in this report must be factual, balanced and non-promotional.

#### **General Instructions**

- (a) Prepare this Monthly Progress Report using the format set out below. The sequence of questions must not be altered, nor should questions be omitted or left unanswered. The answers to the items must be in narrative form. State when the answer to any item is negative or not applicable to the Issuer. The title to each item must precede the answer.
- (b) The term “Issuer” includes the Issuer and any of its subsidiaries.
- (c) Terms used and not defined in this form are defined or interpreted in Policy 1 – Interpretation and General Provisions.

#### **Report on Business**

1. Provide a general overview and discussion of the development of the Issuer’s business and operations over the previous month. Where the Issuer was inactive disclose this fact.

**The Company continued to implement operational initiatives to meet the following business objectives:**

- **The clearance of its U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) application to test its lead product Ortho-R for rotator cuff tear repair in human following the designation by the FDA Office for Combination Products that Ortho-R is a Drug/Biologic combination product.**
- **The prosecution of its patent families in prominent world markets.**

2. Provide a general overview and discussion of the activities of management.

**During the period, Management:**

- On August 17, 2021, The Company received, a “Continue Clinical Hold” letter from the FDA following its July 19, 2021, response on the original clinical hold for five CMC-related requests. The Continue Clinical Hold letter referred to two unsatisfactory clarification/conformity related to elemental and small molecule impurity testing.
- The Company worked with its U.S. CMC testing experts on the new FDA requests related to advanced methods of elemental and small-molecule impurities characterization testing used in the CMC processes. On September 2, 2021, we responded to the Continue Clinical Hold letter by submitting additional clarification on elemental impurities identification and quantification testing methods to the FDA. Secondly, we accepted the FDA’s recommendation to use GC-LC-MS for small molecule impurities testing instead of HCLP-PAD used by our CMC manufacturer. This new testing method is ongoing, and results will be available within a few weeks. The Company is confident that its response to the Continue Clinical Hold letter will address both the requirements for clarifications and address the deficiencies to the complete and final satisfaction of the FDA.
- Concurrently as a proactive step, the Company has requested a type A meeting with the FDA, should the FDA still request further clarification on the proposed elemental impurities testing method. This meeting would involve the participation of our U.S CMC testing experts that use the same IPC-MS testing method for their other Biopharma industry clients for drugs and biologics when submitting INDs to the FDA. The type A meeting would be scheduled by the FDA within 30 days after our response to the continue clinical hold letter (September 2, 2021).
- The Company continued working on the selection and preparation of the clinical sites that would be involved in the Ortho-R Phase I/II clinical trial. So far, eight sites have already been qualified, and Investigational Review Board (“IRB”) applications have been submitted. Four other U.S. sites are still being qualified, so that we can reach our targeted 10-12 sites to participate in our Rotator Cuff Tear repair clinical trial. We still aim to start patient enrolment this fall, after IND clearance by the FDA.
- Executed any activities required to support the above initiatives, either internally or through the company’s partners and key suppliers.
- Continued to actively promote itself to strategic partners interested in our biopolymer technology and/or active programs; and
- Continued to actively promote the Company to potential institutional and retail investors as well as healthcare-life science investment bankers and analysts to facilitate raising the capital required to fund its operations and upcoming clinical programs.

3. Describe and provide details of any new products or services developed or offered. For resource companies, provide details of new drilling, exploration or production programs and acquisitions of any new properties and attach any mineral or oil and gas or other reports required under Ontario securities law.

**Nothing applicable during the period.**

4. Describe and provide details of any products or services that were discontinued. For resource companies, provide details of any drilling, exploration or production programs that have been amended or abandoned.

**Nothing applicable during the period.**

5. Describe any new business relationships entered into between the Issuer, the Issuer's affiliates or third parties including contracts to supply products or services, joint venture agreements and licensing agreements etc. State whether the relationship is with a Related Person of the Issuer and provide details of the relationship.

**Nothing applicable during the period**

6. Describe the expiry or termination of any contracts or agreements between the Issuer, the Issuer's affiliates or third parties or cancellation of any financing arrangements that have been previously announced.

**Nothing applicable during the period.**

7. Describe any acquisitions by the Issuer or dispositions of the Issuer's assets that occurred during the preceding month. Provide details of the nature of the assets acquired or disposed of and provide details of the consideration paid or payable together with a schedule of payments if applicable, and of any valuation. State how the consideration was determined and whether the acquisition was from or the disposition was to a Related Person of the Issuer and provide details of the relationship.

**Nothing applicable during the period.**

8. Describe the acquisition of new customers or loss of customers.

**Nothing applicable during the period.**

9. Describe any new developments or effects on intangible products such as brand names, circulation lists, copyrights, franchises, licenses, patents, software, subscription lists and trademarks

**Nothing applicable during the period.**

10. Report on any employee hiring's, terminations or lay-offs with details of anticipated length of lay-offs.

**Nothing applicable during the period.**

11. Report on any labour disputes and resolutions of those disputes if applicable.

**Nothing applicable during the period.**

12. Describe and provide details of legal proceedings to which the Issuer became a party, including the name of the court or agency, the date instituted, the principal parties to the proceedings, the nature of the claim, the amount claimed, if any, if the proceedings are being contested, and the present status of the proceedings.

**Nothing applicable during the period.**

13. Provide details of any indebtedness incurred or repaid by the Issuer together with the terms of such indebtedness.

**Nothing applicable during the period**

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14. Provide details of any securities issued and options or warrants granted.  
**Nothing applicable during the period**
15. Provide details of any loans to or by Related Persons.  
**Nothing applicable during the period.**
16. Provide details of any changes in directors, officers or committee members.  
**Nothing applicable during the period**
17. Discuss any trends which are likely to impact the Issuer including trends in the Issuer's market(s) or political/regulatory trends.

**The outbreak of a novel strain of the coronavirus, ("COVID-19"), has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures have caused material disruption to businesses globally resulting in an economic slowdown which may impact some of the operational initiatives we are currently pursuing in order to meet our business objectives. Those initiatives include planning activities for the filing of a US FDA IDE, completing the pre-clinical histology samples analysis final report, continuing cGMP manufacturing scale up activities, executing the ORTHO-R Clinical study plan for rotator cuff repair and our ability to timely secure access to supplies. As of today, we have been mildly impacted by the COVID-19 outbreak and we continue to interact with the scientific, medical and financial communities to mitigate as best as possible any impact that could affect negatively our timelines. Our employees, their families as well as our outsourced collaborators are the most important assets we have, and we are taking all actions to protect and accommodate them during these challenging times.**

### **Certificate of Compliance**

The undersigned hereby certifies that:

1. The undersigned is a director and/or senior officer of the Issuer and has been duly authorized by a resolution of the board of directors of the Issuer to sign this Certificate of Compliance.
2. As of the date hereof there were no material information concerning the Issuer which has not been publicly disclosed.
3. The undersigned hereby certifies to the Exchange that the Issuer is in compliance with the requirements of applicable securities legislation (as such term is defined in National Instrument 14-101) and all Exchange Requirements (as defined in CNSX Policy 1).
4. All the information in this Form 7 Monthly Progress Report is true.

Dated: September 7th, 2021

Ortho Regenerative Technologies Inc.  
*/s/ Luc Mainville*  
Senior VP & Chief Financial Officer  
Official Capacity

<b>Issuer Details</b>	For Month End	Date of Report
Name of Issuer Ortho Regenerative Technologies Inc.	August 2021	YY/MM/D 2021/09/07
Issuer Address 16667, Boul. Hymus,		
City/Province/Postal Code Kirkland, Quebec, H9H 4R9	Issuer Fax No. 514.694.0443	Issuer Telephone No. 514.694.0865
Contact Name Luc Mainville	Contact Position Sr. VP & CFO	Contact Telephone No. (514) 693-8854
Contact Email Address <a href="mailto:mainville@orthorti.com">mainville@orthorti.com</a>	Web Site Address <a href="http://www.orthorti.com">www.orthorti.com</a>	