



**ORTHO REGENERATIVE TECHNOLOGIES INC.**

**ANNUAL INFORMATION FORM  
FOR THE FISCAL YEAR ENDED JANUARY 31, 2021**

**May 31, 2021**

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## INTERPRETATION

Unless the context otherwise requires, all references in this Annual Information Form (“AIF”) to “us”, “we”, “our”, “Ortho” or the “Corporation” refer to Ortho Regenerative Technologies Inc.

This AIF should be read in conjunction with Ortho’s audited consolidated financial statements and Management’s discussion and analysis for the fiscal year ended January 31, 2021. The audited consolidated financial statements and Management’s discussion and analysis of the Corporation are available under the Corporation’s profile on SEDAR at [www.sedar.com](http://www.sedar.com). All financial information contained in the AIF have been established in accordance with Canadian generally accepted accounting principles including International Financial Reporting Standards (“IFRS”).

Unless otherwise stated, the information in this AIF is stated as of January 31, 2021.

## CURRENCY AND EXCHANGE RATE INFORMATION

Unless otherwise indicated all references to “\$” or “dollars” in this AIF refer to Canadian dollars.

References to “US\$” or “US dollars” mean United States of America dollars.

The Corporation’s accounts are maintained in Canadian dollars.

## FORWARD-LOOKING INFORMATION

This AIF contains “forward-looking information” within the meaning of applicable Canadian securities legislation. Wherever possible, words such as “plans”, “expects”, or “does not expect”, “budget”, “scheduled”, “estimates”, “forecasts”, “anticipate” or “does not anticipate”, “believe”, “intend” and similar expressions or statements that certain actions, events or results “may”, “could”, “would”, “might” or “will” be taken, occur or be achieved, have been used to identify forward-looking information.

Forward-looking information in this AIF may include, but is not limited to,

- future development activities, and the costs and timing of those activities;
- the Corporation’s anticipated cash needs and its needs for additional financing;
- timing and receipt of approvals, consents and permits under applicable legislation;
- expectations regarding regulatory requirements and developments for its product candidates;
- the Corporation’s ability to conduct successful clinical trials for its product candidates;
- the potential size of markets for the Corporation’s product candidates;
- those related to general economic conditions; and
- the COVID-19 outbreak and its effect on the Corporation’s business.

Forward-looking information is based on the reasonable assumptions, estimates, analysis and opinions of Management as of the date of this AIF made in light of its experience and its perception of trends, current conditions and expected developments, as well as other factors that Management believes to be relevant and reasonable in the circumstances at the date that such statements are made, but which may prove to be incorrect. We believe that the assumptions and expectations reflected in such forward-looking information are reasonable. Readers are cautioned that the foregoing list is not exhaustive of all factors and assumptions which may have been used.

Forward-looking information is subject to known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from those expressed or implied by such forward-looking information. See “Risk Factors”. Although we have attempted to identify important factors that could cause actual results to differ materially from those contained in forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. There is no assurance that such information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such information. Accordingly, readers should not place undue reliance on forward-looking information. We do not undertake to update any forward-looking information, except as, and to the extent required by, applicable securities laws.

## INDUSTRY DATA

Market data and industry forecasts used in this AIF were obtained from various publications. Although Management believes that these independent sources are generally reliable, the accuracy and completeness of such information is not guaranteed and has not been independently verified.

## DEFINITIONS

<b>AIF</b>	Annual Information Form
<b>AMF</b>	<i>Autorité des marchés financiers</i>
<b>Board</b>	Board of Directors of the Corporation
<b>CBCA</b>	Canada Business Corporations Act, RSC 1985, c. C-44, and all regulations made thereunder, as amended
<b>cGMP</b>	Current “Good Manufacturing Practices” which are the standards established by health authorities under which drugs can be developed, manufactured, packaged, analyzed, stored and shipped
<b>CEO</b>	Chief Executive Officer
<b>CFO</b>	Chief Financial Officer
<b>Chairman</b>	Chairman of the Board of Directors
<b>CMC</b>	Chemistry Manufacturing Practice
<b>CMO</b>	Contract Manufacturing Organization
<b>CRO</b>	Clinical Research Organization
<b>CSE</b>	Canadian Securities Exchange
<b>FDA</b>	Food and Drug Administration (U.S.)
<b>FY</b>	Fiscal Year
<b>IFRS</b>	International Financial Reporting Standards as issued by the International Accounting Standards Board
<b>IND</b>	Investigational New Drug Application with the FDA
<b>Management</b>	Senior officers of the Corporation, as a group
<b>Manitex</b>	Manitex Capital Inc.
<b>MCRA</b>	MCRA, LLC, a U.S. based orthopedic specialty CRO
<b>MRI</b>	Magnetic Resonance Imaging
<b>MTA</b>	Material Transfer Agreement
<b>Ortho</b>	Ortho Regenerative Technologies Inc.
<b>Ortho-C</b>	Ortho’s proprietary biopolymer for articular cartilage repair
<b>Ortho-M</b>	Ortho’s proprietary biopolymer for meniscus repair
<b>Ortho-R</b>	Ortho’s proprietary biopolymer for rotator cuff repair
<b>Ortho-V</b>	Ortho’s proprietary biopolymer for osteoarthritis healing
<b>OTCQB</b>	Venture Market of the U.S. OTC Markets Exchange
<b>Person</b>	An individual, sole proprietorship, body corporate, firm, partnership, limited partnership, unincorporated organization or association, trust, or any other legal or commercial entity
<b>Phase I/II RCT trial</b>	Phase I/II clinical trial for testing Ortho-R for Rotator Cuff Tear repair, to take place in the U.S.
<b>Polytechnique</b>	Polytechnique Montréal
<b>Polyvalor</b>	Polyvalor, Limited Partnership
<b>PRP</b>	Platelet-rich plasma
<b>Pre-RFD</b>	Pre-request for designation
<b>Option Plan</b>	A share option plan approved by the Board
<b>Regulatory Authority</b>	Any board, commission, association or other body, organization or agency, whether governmental, professional, self-regulatory or otherwise, having jurisdiction over the Corporation or over any part of the business carried on by it
<b>Shares</b>	Class “A” shares of Ortho Regenerative Technologies Inc.
<b>Transfer Agent</b>	Computershare Investor Services Inc.
<b>U.S.</b>	The United States of America.

## THE CORPORATION

### Name, address and incorporation

Ortho was incorporated on February 5, 2015 pursuant to the CBCA. The registered office and principal place of business of the Corporation are located at 16667 Hymus Boulevard, Kirkland, Québec, Canada, H9H 4R9. See “*Description of the Business – Facilities*”.

On September 16, 2015, pursuant to Articles of Amendment, the Corporation amended its articles by (i) amending the rights, privileges, restrictions and conditions attached to all “B” shares, and (ii) cancelling of class “C”, “D”, “E”, “F”, “G”, “H”, “I”, “J”, “K”, “L”, “M”, “N”, “O” and “P” shares.

On April 26, 2016, pursuant to Articles of Amendment, the Corporation amended its articles by (i) removing the restrictions on the transfer of its Shares, (ii) adding a legal French version of its name being *Technologies Ortho Régénératives inc.* and (iii) adding a provision to have the ability to appoint one or more additional directors between shareholders meetings.

The Corporation’s Shares are publicly traded on the CSE under the symbol “*ORTH*”, as well as on the OTCQB market under the symbol “*ORTIF*”. The Corporation has 34,567,600 Shares that are issued and fully paid as at January 31, 2021.

### Intercorporate relationships

The Corporation has no subsidiaries.

## GENERAL DEVELOPMENT OF THE BUSINESS

### Three-Year History

#### Developments in fiscal year 2019 (February 1, 2018 - January 31, 2019)

In the period, Management was primarily focusing on: i) Capital markets initiatives aimed at broadening the Corporation’s shareholder base, and raising capital; ii) Activities relating to the pre-clinical and clinical development path for our lead product Ortho-R, and more specifically the commencement of a large 48 animal pivotal trial, representing the last planned study prior to advancing our product into human trial stage; iii) Technology transfer and scale-up activities of our manufacturing process, including securing cGMP grade material to conduct our animal pivotal trial; iv) Submission of a pre-IND package and questions with the FDA in anticipation of our first Human Proof-of-Concept (“POC”) trial for Ortho-R (Phase I/II); and v) Initiate formal discussions with potential CROs for our Phase I/II human trial.

On June 13, 2018 the Corporation announced positive outcomes data from a preclinical pilot study examining its Ortho-R technology in the biologic repair of rotator cuff injuries. In this study, treatment with Ortho-R was shown to improve healing versus standard of care, with the highest Ortho-R dose having the greatest effect. Treatment with Ortho-R showed improvements in the structural organization of the tendon and the structural appearance of the tendon insertion site. In addition, Clinical signs and histopathology showed no treatment-specific adverse effects, suggesting high safety of Ortho-R.

On July 19, 2018 the Corporation announced that it has issued a total of 450,000 Shares pursuant to the second tranche (the “Second Tranche”) of its previously announced non-brokered private placement. Pursuant to the Second Tranche, a total of 150,000 of the Shares were sold at a price per share of \$0.40 and Manitex, an insider of Ortho, converted \$120,000 in principal balance owed to the Corporation into 300,000 Shares at a conversion price per share of \$0.40.

On July 31, 2018 the Corporation announced the extension of the expiry date of certain warrants which were issued in connection with private placements that closed prior to the listing of Ortho’s shares on the CSE. The extended warrants, representing an aggregate of 2,107,500 warrants, originally expired in 2018 and 2019. Pursuant to the Warrant Term Extension, the expiry dates of the Warrants issued in conjunction with the Private Placements closed on August 3, 2016, March 31, 2017, April 27, 2017, June 28, 2017 and July 27, 2017 were extended for one (1) year from their respective original maturity dates. All other terms of the Extended Warrants remained unchanged.

The Corporation entered into an agreement with a leading CMO within the global biopharmaceutical industry to commence work on providing the Corporation with cGMP finished dosage form quantities of Ortho-R for currently planned clinical trials and strategic partnering initiatives.

On September 19, 2018 the Corporation announced that Luc Mainville was appointed Chief Financial Officer.

During the period the Corporation announced that a poster, entitled “Freezedried [Ortho-R] in Platelet-rich Plasma in Sheep Model of Rotator Cuff Repair,” was presented at the 39th SICOT Orthopaedic World Congress in Montreal, Canada. The presentation given by Anik Chevrier Ph.D., a researcher from Montreal’s prestigious Polytechnique, highlighted the results of a dose ranging study examining Ortho’s Ortho-R technology in the biologic repair of rotator cuff injuries. The study used histopathology, the microscopic examination of biological tissues in very fine detail, read by two

blinded experts, as well as MRI, to compare the results of Ortho-R versus standard of care in a non-clinical rotator cuff injury model in sheep.

During the period the Corporation entered into a research agreement with a leading Preclinical CRO within the biopharmaceutical industry to commence work on a pivotal study on Ortho-R using an ovine rotator cuff repair model. This study is expected to last approximately 9 months with a final report to be submitted at that time. This CRO is not a related party.

The Corporation announced that its recently completed study has been chosen by a peer reviewed panel as worthy of a podium presentation at the 2019 ICORS (International Combined meeting of Orthopaedic Research Societies) congress in June. ICORS attracts Orthopaedic surgeons, sports medicine specialists, physicians and research scientists from around the globe and is focused on how new discoveries translate into improved clinical care. The podium presentation will feature the study titled "Freeze-dried chitosan solubilized in platelet-rich plasma in a sheep model of rotator cuff repair"

The Corporation also announced that it had submitted a formal pre-submission package to the FDA seeking guidance after our recent data showed statistically significant results in as little as 3 months. The package included data from all our studies and highlighted that Ortho-R has shown structural improvements at 6 months and as a second clinical benefit has showed improved speed of healing as evidenced by our 3-month data. Over the same time period our Intellectual Property assets continued to grow with progress on multiple patent files as well as another European patent issuing in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, Italy, Netherlands, Norway, Spain, Sweden, Switzerland & Liechtenstein, and the United Kingdom.

Our technology transfer to production and scale-up has progressed through a critical milestone with our first finished product lots in the process of being completed.

We initiated planning activities for an animal POC study relating to the use of our Ortho-R product for the treatment/repair of meniscus tear. We continue to explore alternative use for our proprietary bioactive polymer outside of the soft tissue injury repair applications.

#### **Developments in fiscal year 2020 (February 1, 2019 - January 31, 2020)**

In February 2019, the Corporation had a formal pre-IND meeting with the FDA. The meeting confirmed the timelines to complete pre-IND requirements. The meeting also confirmed that all aspects relating to product characterization, safety and toxicology were in order, representing significant savings for the Corporation.

Results of two key scientific studies validating Ortho-R's ability to improve the repair of two distinct joint tissues - the rotator cuff tendon and articular cartilage, were presented at the 2019 Annual Orthopaedic Research Society ("ORS") meeting in Austin, Texas. The studies highlighted the results of a dose ranging study examining Ortho-R technology in the biologic repair of rotator cuff injuries. The study used MRI and histopathology (the microscopic examination of biological tissues in very fine detail), read by blinded experts, to compare the results of Ortho-R versus standard of care in a non-clinical rotator cuff injury model in sheep. It showed that Ortho-R improved rotator cuff healing processes in this large animal model, as revealed by MRI and trends of improved structural appearance of the tendon and enthesis at 12 weeks post-op.

On March 6, 2019, the Corporation announced the appointment of Mr. Steve Saviuk as Chairman of the Board. Dr. Brent Norton, who previously held this position, remains on the Board and continues to lead the Corporation as its President and Chief Executive Officer. The Corporation also announced on the same date the resignation of Ms. Sharon Ludlow from the Board.

On April 25, 2019 the Corporation announced the extension of the term of certain warrants of the Corporation which were issued in connection with a private placement closed in October 2017.

On June 17, 2019, the Corporation announced the nomination of Claude LeDuc as its new President and CEO in replacement of Dr. Brent Norton who is stepping down from his operational role to focus on other initiatives. Dr. Norton will remain on the Board of the Corporation. On June 20th, the Corporation announced the appointment of Messrs. Pierre Laurin and Claude LeDuc to its Board. The nominations are effective as of June 19, 2019.

On August 14, 2019 the Corporation announced that following the start of a 6-month pivotal preclinical study in January 2019, it successfully completed the in-life portion of the study as well as data collection required for submitting the IND for its Rotator Cuff program.

On August 28, 2019 the Corporation announced that it had entered into a collaborative MTA with a leading global Orthopaedic Corporation (the "Partner"). Under the terms of the MTA, a formulation of the Partner's commercial product will be evaluated for its properties when used in conjunction with Ortho-R.

On August 2, 2019, the Corporation extended the term of 460,000 warrants, each having an exercise price of \$0.70, that were set to expire on August 2, 2019. The expiry date of these warrants has been extended to August 2nd, 2020. All other terms of the extended warrants remain unchanged.

On September 12, 2019, the Corporation announced that it had selected MCRA, LLC as its U.S.-based orthopaedic specialty CRO, to conduct its upcoming Phase I/II rotator cuff Ortho-R human trial. Ortho-R utilizes Ortho's proprietary RESTORE technology platform, which consists of a mucoadhesive CHITOSAN based biopolymer matrix mixed with patient conditioned plasma of a concentrate of proteins/growth factors to deliver biologics to increase the healing rates of occupational and sports related injuries. The Ortho-R Phase I/II clinical trial plans to enroll 75 patients, randomized across 3 arms of 25 patients across multiple sites in the US. MCRA is a leading advisory firm and CRO focusing on the neuro-musculoskeletal industry. MCRA has key relationships with hundreds of US surgical sites and has helped more than 600 companies including the top 10 largest US Orthopaedic companies. MCRA will be integrating regulatory and reimbursement expertise in conjunction with its CRO services for the Ortho-R Phase I/II clinical program.

On September 17, 2019, the Corporation announced the extension of the term of certain warrants of the Corporation which were originally issued in March 2017 in connection with a private placement. The Extended Warrants, representing an aggregate of 480,000 warrants, originally expired on October 1, 2019. Pursuant to the Warrant Term Extension, the expiry date of the Warrants is extended for one (1) year, being October 1, 2020. All other terms of the Extended Warrants will remain unchanged.

On October 9, 2019, the Corporation announced that it had closed a non-brokered \$1.6 million private placement of convertible debenture units (the "Private Placement") consisting of \$750,000 of subscriptions and \$894,000 from conversion of loans from Manitex. The Corporation issued 1,644 unsecured convertible debenture units (the "Units") at a purchase price of \$1,000 per Unit for gross proceeds of \$1,644,000. Each Unit consist of one 10% unsecured convertible debenture for a principal amount of \$1,000 (each, a "Debenture") convertible at a \$0.30 price per Class "A" share of the Corporation ("Common Share") and 2,000 Common Share purchase warrants (each, a "Warrant"), with an exercise price of \$0.50 ("Exercise Price"), representing a 60% warrant coverage. The Warrants will automatically convert into Common Shares of the Corporation at the Exercise Price if the volume weighted average price over any 20 consecutive trading days is greater or equal to \$1.00. Both the Debentures and the Warrants have a maturity date of October 8, 2021.

On October 15, 2019 the Corporation announced the extension of the term of certain warrants (the "Extended Warrants") which were originally issued in April 2017 in connection with a private placement. The Extended Warrants, representing an aggregate of 570,000 warrants, originally expired on October 29, 2019. Pursuant to the Warrant Term Extension, the expiry date of the Warrants is extended for one (1) year, being October 29, 2020. All other terms of the Extended Warrants remained unchanged.

On December 12, 2019, the Corporation announced the extension of the term of certain warrants which were originally issued in June 2017, July 2017 and October 2017 in connection with private placements. The Extended Warrants, representing an aggregate of 207,500, 390,000 and 905,000 share purchase warrants of the Corporation, originally expiring on December 28, 2019, January 28, 2020 and April 29, 2020 respectively. Pursuant to this extension, the expiry date of the Extended Warrants is extended for one year, being December 28, 2020, January 28, 2021 and April 29, 2021. All other terms of the Extended Warrants remained unchanged.

#### **Developments in fiscal year 2021 (February 1, 2020 – January 31, 2021)**

The Corporation continued to implement operational initiatives to meet its business objectives including the execution of its pre-clinical development plan, planning activities for the filing of a US FDA Investigational Device Exemption (IDE) to test its lead product Ortho-R for rotator cuff repair in human, and prosecution for its patent families. The Corporation also reported 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. Ortho has now completed its preclinical program in rotator cuff tear repair with the accomplishment of two studies in large animals.

The outbreak of a novel strain of the coronavirus, ("COVID-19") 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 impacted some of our operations. Those included 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.

On April 21, 2020, the Corporation closed a non-brokered \$1.1 million private placement of convertible debenture units (the "Private Placement") by issuing 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 consisted of one 10% unsecured convertible debenture in the principal amount of \$1,000 (each, a "Debenture") convertible at a \$0.30 price per Share of the Corporation and 2,000 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 Share at an exercise price of \$0.50 ("Exercise Price"). The

Warrants will automatically convert into Common Shares of the Corporation at the Exercise Price in the event that the volume weighted average price over any 20 consecutive trading days is greater or equal to \$1.00. Both the Debentures and the Warrants have a maturity date of April 21, 2022. The securities issued under the Private Placement are subject to a statutory hold period in Canada of four months and one day. 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.

The Corporation entered into a strategic and licensing agreement with Ingenew Pharmaceuticals Inc. The Agreement will explore the expansion of the scope of the Corporation's proprietary technological platform applications to include the delivery of therapeutics.

The Corporation announced on June 22, 2020 the appointment of Mr. Michael Atkin as its new independent Chairman of the Board. Mr. Atkin is succeeding Mr. Steve Saviuk who will continue to serve the Corporation as a Board member.

The Corporation issued 245,000 stock options to its Chief Executive Officer. The stock options have an exercise price of \$0.37 and vest over 3 years, with a maturity date of 5 years after the grant. The pricing and vesting terms of the options were set in accordance with the Corporation's Stock Option Plan. Furthermore, the Corporation also issued 2 million warrants with an exercise price of \$0.50 per Common Share and expiring July 31, 2021 as compensation to nonrelated parties providing social media support and corporate branding services.

On August 6, 2020, the Corporation announced that it received from the U.S. FDA Office of Combination Products, the Ortho-R product designation as a Drug/Biologics combination product. Ortho-R has various physicochemical interacting actions on various cell types and other PRP components, therefore supporting a combination product with the Ortho-R reconstituted in PRP is considered a Drug/Biologics that is delivered through accessory Devices. The product's jurisdictional assignment is to the FDA's Center for Biologics and Research (CBER). The required Investigational New Drug (IND) regulatory application to start the Ortho-R U.S. Rotator Cuff Tear repair clinical trial, would be completed and submitted to FDA during Q3 & Q4-20 (calendar year).

On August 24, 2020, the Corporation closed a non-brokered \$2.5 million private placement of units (the "Private Placement"). The Corporation issued 7,733,812 units (the "Units") at a purchase price of \$0.32 per Unit for total gross proceeds of \$2,474,820. Each Unit consists of one (1) Share of the Corporation and one (1) Share purchase warrant of the Corporation (a "Warrant"). Each Warrant is exercisable into one (1) Share in the capital of the Corporation (a "Warrant Share") at the price of \$0.50 per Warrant Share for a period of 36 months from closing. In the event that the daily VWAP over any twenty (20) consecutive trading days is greater or equal to \$1.00, the Corporation may give notice to the Warrant holder, at any time after February 5, 2021, that all remaining Warrants must be exercised within a period of 30 days from the date of receipt of the notice, failing which the Warrants will automatically expire. The Common Shares and the Warrants issued under the Private Placement were subject to a statutory 4-months hold period under the applicable securities laws. The Corporation paid \$51,366 in finder's fees in connection with the Private Placement. No broker or agent was involved in the transaction. The net proceeds of the Offering were used to fund the following ongoing value creation activities: i) Securing FDA's approval to start our U.S. clinical trial on Ortho-R for rotator cuff tear repair; ii) Manufacturing GMP Clinical Trial batch for Ortho-R; iii) Completing US clinical trial investigation sites selection, setting, and training; iv) Starting U.S. clinical trial patients enrolment activities 5) Secure U.S. exchange listing for Ortho's Shares 6) General and administrative corporate purposes.

On September 2, 2020, the Corporation closed a \$137,600 additional non-brokered private placement of 430,000 units under the same terms and follows the closing of a non-brokered and oversubscribed \$2.5 million private placement of units completed on August 24, 2020 bringing the overall gross proceeds raised through the two private placements to \$2.6 million.

On October 28, 2020, the Corporation announced that Ortho's shares will start trading on the OTCQB venture market in the United States under the symbol "ORTIF". The OTCQB facilitates access to our securities for U.S. institutional and retail investors. This listing is part of the Corporate strategy to broaden its shareholder base while increasing liquidity.

On October 19, 2020, the Corporation announced the appointment of Mukesh Ahuja, MBBS, MSc as its new Vice-President Clinical and Medical Affairs, effective November 1, 2020.

On November 30, 2020, the Corporation completed a non-brokered private placement of secured non-convertible debenture units for gross proceeds of \$3.0 million (the "Offering"), including \$350,000 from insiders and employees. The Corporation issued 3,000 secured non-convertible debenture units (the "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 Corporation in the principal amount of \$1,000 (each a "Debenture") and 500 Class "A" Share purchase warrants (each a "Warrant"). The units issued as part of the Offering will mature on November 30, 2023. Each Warrant entitles the holder thereof to purchase one Class "A" of the Corporation at an exercise price of \$0.75 at any time up to 36 months following the closing date of the Offering. The Debenture Units are subject to a statutory hold period under the applicable securities laws and in such case the certificates evidencing the securities will bear a legend to that effect, as applicable. The Corporation paid \$127,500 in commissions and issued 170,850 broker warrants in

connection with the Offering, in compliance with applicable securities laws. 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.

On January 5, 2021, the Corporation announced having entered into a global licensing agreement (the "Agreement") with Hanuman Pelican Inc. ("Hanuman") for the use of the Buoy Suspension Fractional System in combination with Ortho-R. 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). Hanuman will also supply its Buoy Suspension Fractional System as the exclusive Platelet Concentration System to be used in Ortho's clinical trial at each clinical site participating in the upcoming US Ortho-R phase I / II clinical trial for rotator cuff tears repair. Ortho will pay royalties on net sales of the Buoy Suspension Fractional System portion of the combined Ortho-R package.

#### **Subsequent events (after January 31, 2021)**

On February 4, 2021, the Corporation announced that it had retained Westwicke, an ICR company, as its investor relations advisors for the U.S. markets. On February 10, 2021, the Corporation announced the launch of a 12-month online investors outreach campaign through AGORACOM for the purposes of broadening its shareholder base and targeting new investors that would be specifically interested in the Company's business model, as well as engaging current shareholders. The Corporation agreed to pay 100% of Agoracom's fees for the above-mentioned services by issuing fully-paid and non-assessable Shares.

On February 24, 2021, the Corporation announced the appointment of Patrick O'Donnell to its Board, effective February 24, 2021. The Corporation granted 100,000 options to Mr. O'Donnell. The Corporation also announced the retirement of Professor Michael Buschmann and Professor Caroline Hoemann from its Board of Directors, effective February 22, 2021.

On March 31, 2021, the Corporation announced having secured DTC eligibility for its shares listed on the OTCQB market in the U.S. and trading under the symbol "ORTIF".

On April 6, 2021, the Corporation announced that it has submitted an IND application to the FDA for the initiation of a Phase I/II clinical trial of Ortho-R in rotator cuff tear repair.

## **DESCRIPTION OF THE BUSINESS**

The Corporation is an emerging Orthopaedic and Sports Medicine orthobiologics Corporation dedicated to the development of novel therapeutic soft tissue repair technologies to dramatically improve the success rate of orthopedic and sports medicine surgeries. The Corporation's proprietary biopolymer has been specifically designed to increase the healing rates of occupational and sports related injuries to tendons, ligaments, meniscus, and cartilage. The biopolymer – autologous PRP combination implant, designated by the U.S. FDA, as a Drug/Biologics combination product, can be directly placed into the site of injuries by surgeons during routine operative procedures without significantly extending the duration of surgeries and without further interventions. The Corporation's technology was developed by the Biomaterials and Cartilage Laboratory at Polytechnique, and senior researchers at Polytechnique are still actively involved in the day-to-day development of Ortho's pipeline.

#### **Development Pipeline**

Ortho's pipeline includes four active R&D projects:

## Development Stage

Program	Indication	Details
Ortho-R	Rotator Cuff tear repair	Ortho-R is Ortho's lead program. Ortho-R is a biopolymer-PRP bioactive implant, specifically designed to guide and accelerate the repair of various musculoskeletal conditions. We are aiming to assess the clinical efficacy of Ortho-R, initially for Rotator Cuff tear repair. Ortho-R can also be used to accelerate the healing of other soft tissues such as ligaments and meniscus (see Ortho-M).
Ortho-M	Meniscus	Testing the efficacy of our biopolymer-PRP bioactive implant for meniscus repair. Efficacy of our product has already been demonstrated in a large animal pilot study. Over the coming year we are aiming at validating our model in a large animal pivotal study which would facilitate entering into human clinical trial.
Ortho-C	Cartilage repair	Testing our freeze-dried matrix with ultra-high porosity designed to augment bone marrow stimulation procedures for articular cartilage repair, including microfracture and drilling. Efficacy of our product has already been demonstrated in a preclinical pilot study.

## Feasibility Stage

Program	Indication	Details
<u>Ortho-V</u>	Osteoarthritis	Feasibility research on a freeze-dried biopolymer formulation combined with autologous biologics, tailored for intra-articular injections to provide visco-supplementation of articular joints and potentially gain disease modification outcomes in applications such as Osteoarthritis

Considering the significant bioactivity and residency of our proprietary biopolymer – PRP implants, Ortho continues to assess its potential for therapeutic uses outside of the soft tissue repair market. The Company have joined the Biomaterials and Cartilage Laboratory at Polytechnique, in submitted grant applications to develop new Drug/Biologics formulations for both Osteoarthritis and a wound care.

### Ortho-R for Rotator Cuff tear repair

Ortho-R is a patent protected freeze-dried formulation that contains a biopolymer, a lyoprotectant and a clot activator. This freeze-dried formulation can be solubilized in PRP to form injectable bioactive implants that coagulate after implantation. Extensive in vitro testing has allowed the Corporation to identify specific formulations that meet the criteria for optimal commercial products:

- (i) rapid and complete solubilization in PRP;
- (ii) biopolymer-PRP mixtures having paste-like handling properties desired by surgeons;
- (iii) biopolymer-PRP mixtures that coagulate rapidly to form solid biopolymer-PRP hybrid biologics implants;
- (iv) biopolymer-PRP biologics implants that are mechanically stable and resist platelet-mediated clot retraction; and
- (v) dispersion of the biopolymer in the implants that is homogenous for optimal biodegradability.

The use of Ortho-R in conjunction with standard of care suturing techniques produced promising histological findings in small and large animal models, which is expected to translate into superior rotator cuff repair for humans. No adverse events were found in any of the above-mentioned animal studies, which suggests a high level of safety. Progress made during the recent quarters have set the stage for achievements of major corporate/regulatory/strategic milestones over the current and upcoming calendar years.

### Preclinical:

Earlier in FY-21, we have successfully completed the preclinical pivotal study's safety and clinical histology analysis, statistical analysis and final report. The study's final report confirmed the safety of Ortho-R as well as the evidence that our biologics hybrid implant delivered as an adjunct to standard of care surgery, improves tendon, tendon insertion site and overall repair in Rotator Cuff Tear repair compared to standard of care surgery alone. [https://www.orthorti.com/cms\\_files/phpfQwJvt.pdf](https://www.orthorti.com/cms_files/phpfQwJvt.pdf).

### Regulatory:

In Q2-21, the Corporation received from the U.S. FDA Office of Combination Products, the Ortho-R designation as a Drug/Biologics combination product. Ortho-R has various physicochemical interacting actions on various cell

types and other PRP components, therefore confirming a drug/biologics combination status. The product's jurisdictional assignment is to the FDA's Center for Biologics Evaluation and Research (CBER). There are multiple merits of a Drug/Biologics therapeutic combination product. One of them is the ability to have a multiple mode of action label, related to the various interactions between our proprietary biopolymer and PRP, which may justify the scientific rationale behind the product's therapeutic effect.

The required IND submission to start our Phase I/II RCT trial has been completed and submitted to the FDA in April 2021. We expect to receive clearance from the FDA to initiate the testing of Ortho-R for rotator cuff tear repair in human in Q2-2021.

#### Manufacturing & CMC:

The cGMP clinical lot production required to support the Phase I/II RTC trial was completed in April 2021 and released in May 2021.

#### Clinical Program:

We continued working with MCRA from Washington D.C., our U.S. CRO, in charge of managing our US multi-center Phase I/II clinical trial. Activities focus were mainly on protocol, patients' assessment EDC system, MRI procedure protocol and system, clinical sites considerations and qualification. Clinical trial patients' enrollment is expected to start in Q3-2022 (Calendar), after IND submission approval by the FDA and Clinical Review Boards (CRB) approvals from the various clinical testing centers to be involved in the Phase I/II RCT trial.

As at May 31, 2021, eight (8) US-based clinical testing centers had committed to participate in the Phase I/II RCT trial, with 4 more under assessment.

The following table provides a summary of the past and projected corporate and development milestones for the 2019-2022 calendar years and quarters.



## **Orthopedic Regenerative Medicine Market**

According to Coherent Market Insights, the global orthopedic regenerative medicine market is estimated at \$7.1B in 2020 and projected to \$15.2B in 2027. The major application are bone, cartilage, spine, ligament and tendon repair with respective estimated markets at \$2.8B, \$1.9B, \$1.9B, \$500M and \$400M. The global market shares are North America 49%, Europe à 24% Asia Pacific 20% and others 7%.

The actual technologies used in these musculoskeletal conditions are various cell-based stem cells harvested from bone marrow aspirate, adipose tissue, umbilical cord tissue and the use of synthetic bone substitutes, allograft and autograft substitutes and PRP. Cell-based and graft substitutes options are expensive and have cumbersome manufacturing / processing methods which needs extensive quality control regulatory processes. The Ortho-R Drug-PRP combination product, has a very competitive manufacturing costs, is easily available to orthopedic surgeons as an off the shelf lyophilized drug, which is easy to mixt in the operating room or orthopedic clinics with the patients' autologous PRP. The Ortho-R combination product is then used as an adjunct to standard of care surgery, and delivered with a syringe and needle, directly on the surgically repaired site to accelerate and augment new tissue repair in various musculoskeletal conditions such as tendon, ligament and meniscus tears, and cartilage lesions.

The Corporation's two main soft tissue repair competitors are:

- Carmell Therapeutics Corporation is developing bone healing and tissue accelerant for bone, tendon and wound healing. Their Plasma-Based Bioactive materials manufactured from donor's blood plasma, contains concentrated regenerative factors. They have completed a Phase II study in adjunctive treatment for long bone fracture. Other applications are in preclinical stage.
- Histogen Inc. has developed a cell conditioned media, and extracellular matrix material produced by hypoxia-induced pluripotent cells. They have three product candidates in clinical stage intended to address hair loss, a dermal filler and a treatment for cartilage repair.

## **Orthopedic Platelet-Rich Plasma Market**

The global orthopedic Platelet-Rich Plasma (PRP) Market is estimated by Coherent Market Insights, to US \$102M in 2020, \$131M in 2023 and \$188M in 2027. The limited residence time of PRP is a limiting factor for a broad use adoption by the orthopedic community. Ortho Regenerative Technologies have developed a Novel Drug/Biologics combination product that increase significantly the residence time, hence the biologic activity of PRP in soft tissue repair applications. The company have demonstrated in studies that Ortho-R increases the PRP bioactivity time in vitro and in nonclinical in-vivo studies, resulting in an accelerated and augmented tissue repair in Rotator Cuff Tear (RCT) repair in sheep. The Company is starting a Phase I/II multi-center clinical study in the US, to evaluate Ortho-R as an adjunct to standard of care surgery, in Rotator Cuff Tear Repair. The goal is to decrease the high failure rate and thus improve patient outcomes of standard of care surgery in RCT repair.

## **RISK FACTORS**

An investment in Shares of the Corporation involves a number of risks. Readers should carefully consider the risks and uncertainties described below, together with all of the other information included in this AIF. If any of the following risks actually occurs, the Corporation's business, financial position or results of operations could be materially adversely affected. In such an event, the value of the Shares could decline. Additional risks and uncertainties that we do not presently know about or that we currently believe to be immaterial may also adversely impact our business, financial condition, results of operation or the value of your Shares.

### **Public Company and possible volatility of share price**

No assurance can be given regarding the liquidity of any public market for Ortho Common Shares or that the Corporation will continue to meet the listing requirements of the CSE or the OTCQB. The market prices for securities of drug delivery, biotechnology and pharmaceutical companies have historically been highly volatile. The market price of Ortho Common Shares can be subject to wide fluctuations in response to, among other things, variations in operating results, the Corporation's ability to execute its business plan, competition and other events or factors. Trading prices of the Ortho Common Shares may be influenced by many factors, including, without limitation: investor perception of the Corporation; expectations regarding any potential future acquisitions or sales of Ortho Common Shares by one or more shareholders; market conditions relating to the Corporation's segment of the biotechnology or pharmaceutical industry or the securities markets in general; research analyst recommendations and the Corporation's ability to meet or exceed performance expectations of analysts or investors; failure of any of the Corporation's third-party collaborators to successfully market and successfully commercialize any of the Corporation's product or product candidates; adverse events affecting the Corporation's manufacturers; announcements of U.S. FDA, Health Canada or other governmental authority approval or non-

approval of products in the Corporation's product pipeline; the results of pre-clinical testing and clinical studies or trials by competitors to the Corporation; changes in government regulations, regulatory decisions or patent decisions; and general market conditions.

### **Regulatory approval of our products**

The Corporation must receive regulatory approval of any product candidate before such candidate can be commercialized. The development required to take a technology from its earliest stages to its incorporation in a product that is sold commercially can take many years and cost a substantial amount of money. The Corporation's technologies can be quite complex, with many different components. Our technology may not perform in the same manner when used for different application and, therefore, these technologies may not prove to be as useful or valuable as originally thought, resulting in additional development work. Delays or unanticipated increases in costs of development at any stage, or failure to solve a technical challenge, could adversely affect the Corporation's operating results. The development and manufacturing of any product candidate developed independently or in collaboration with third parties, as well as the distribution, marketing and record keeping of such product candidate, are regulated by numerous federal, state, provincial and local governmental authorities, principally the U.S. FDA in the United States and Health Canada in Canada, and other similar agencies in other countries. The procedures for obtaining marketing approval of a new product candidate vary among countries. These procedures vary depending on such factors as the novelty of the drug and its intended use. The development and regulatory approval process in each jurisdiction take many years, requires the expenditure of substantial resources, is uncertain and subject to delays. In addition, approval by a regulatory authority of one country does not ensure the approval by regulatory authorities of other countries. Many factors could delay the Corporation's receipt of revenues from the commercialization of its product candidates. Failure to obtain regulatory approval, any delay or setback in obtaining regulatory approval or limitation on drug use required as a condition of approval could adversely affect the Corporation's ability to market any drugs developed independently or with partners; affect the Corporation's ability to negotiate partnership and other agreements; impose additional costs and diminish any competitive advantages that the Corporation may attain; or adversely affect the Corporation's ability to generate new product sales and/or royalties based on these sales.

### **Manufacturing risks**

The Corporation has relied and will continue to rely on third party contractors engaged by the Corporation to support its current and near-term manufacturing needs. If the Corporation is not able to secure suitable third party manufacturing contractors to meet the product quantities required for commercial manufacturing or to support large clinical trials in a timely manner or at a reasonable cost, the Corporation may risk delaying its clinical trials or regulatory approvals, reduction in levels of saleable inventory of the Corporation's products and potentially breaching its obligations under future out-licensing agreements or other commercialization arrangements. Such consequences could have a material adverse impact on the financial position of the Corporation. Similarly, should systems fail, or a disaster strike, the ability to produce products would be negatively affected, which in turn, would also adversely affect the Corporation's business. While the Corporation has manufacturing capacity for its Ortho-R product with third party manufacturers (certain of which are single source in nature), were such facilities to become unavailable for any reason, finding substitute facilities that are properly qualified to handle controlled substances or otherwise capable of serving as a backup supplier may prove difficult and/or result in a significant delay in manufacturing product. Similarly, finding initial backup facilities that are appropriately qualified for its other products may also be problematic. Pharmaceutical manufacturing involves risks and uncertainties related to the demonstration of adequate stability, sufficient purification of drug products, the identification and elimination of impurities, optimal formulations, process validation and challenges in controlling for all of these factors. Finally, to the extent that the manufacturing costs charged by third party contractors increase and such costs are not able to be fully passed on to the Corporation's customers, the profit margins of the Corporation on its products may be adversely impacted.

### **Single supplier risk**

The Corporation may face limited supplies of products, critical trial materials or manufacturing components that may only be obtained from a single or limited number of suppliers. This could result in production delays, substantial lost revenue opportunity, clinical trial delays or contract liability to third parties. Any interruption in the supply of single source material could cause the Corporation to seek alternative sources of supply or to manufacture such components internally, which may impose considerable costs and/or delays on the production of the Corporation's products and product candidates. If the supply of necessary material is interrupted, material from alternative suppliers may not be available in sufficient volumes or at acceptable quality levels within required timeframes, if at all, to meet the needs of the Corporation. Additionally, if the costs of key supplies of materials or manufacturing components increases, the profit margins of the Corporation may be adversely impacted.

### **Raw material sourcing risks**

The Corporation utilizes several raw materials which are subject to price fluctuations beyond its control. Market price fluctuations of these raw materials could have a material adverse effect on the Corporation's financial condition and results of operations. There can be no assurance that the price of the Corporation's raw materials will not increase in the future and, if such increase occurs, that the Corporation will be able to effectively pass the costs associated with such an increase on to its customers.

### **Secured Debt Financing Risks**

All of the assets of the Corporation are subject to a secured interest in favour of a syndicate of lenders – see December 2020 non-convertible debt financing (the “December 2020 NCD”). Consequently, a default under the December 2020 NCD would have a material adverse impact on the Corporation.

The ability of the Corporation to repay its indebtedness under the December 2020 NCD will be contingent upon the Corporation raising sufficient alternative capital or securing other cash proceeds to be able to make the necessary payments. Interest payments under the December 2020 NCD facility are to be made quarterly. A default in paying quarterly interest under the December 2020 NCD would accelerate repayment and may have a material adverse effect on the Corporation.

### **Our business may be adversely affected by the effects of the COVID-19 pandemic.**

In December 2019, a novel strain of coronavirus, SARS-CoV-2, causing a disease referred to as COVID-19, was reported to have surfaced in Wuhan, China. It has since spread to multiple other countries; and, in March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. This pandemic has adversely affected or has the potential to adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate, our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, business partners and customers, and the demand for some of our marketed products. The COVID-19 pandemic has resulted in travel and other restrictions to reduce the spread of the disease, including governmental orders across the globe, which, among other things, direct individuals to shelter at their places of residence, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, maintain social distancing, and order cessation of non-essential travel. As a result of these recent developments, the Corporation has implemented work-from-home policies for its employees. The effects of shelter-in-place and social distancing orders, government-imposed quarantines, and work-from-home policies may negatively impact productivity, disrupt the Corporation's business, and delay business timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on the Corporation and its suppliers and key business partners' such as the Polytechnique de Montreal team's ability to conduct business in the ordinary course. Such restrictions and limitations may also negatively impact the Corporation's access to regulatory authorities (which may be affected, among other things, by travel restrictions and may be delayed in responding to inquiries, reviewing filings, and conducting inspections). The COVID-19 pandemic may also result in the loss of some of key personnel, either temporarily or permanently. These and similar, and perhaps more severe, disruptions in the Corporation's operations may materially adversely impact our business, operating results, and financial condition.

Quarantines, shelter-in-place, social distancing, and similar government orders (or the perception that such orders, shutdowns, or other restrictions on the conduct of business operations could occur) related to COVID-19 or other infectious diseases may be impacting personnel at the Corporation's manufacturing facilities, suppliers, and other third parties on which we rely, and may impact the availability or cost of materials produced by or purchased from such parties, which could result in a disruption in the Corporation's supply chain. In addition, infections and deaths related to COVID-19 may disrupt healthcare and healthcare regulatory systems. Such disruptions could divert healthcare resources away from, or materially delay, FDA review and potential approval of the Corporation's clinical trials or products. It is unknown how long these disruptions could continue. Further, the use of the Corporation's product candidates in clinical trial settings may need to be deprioritized. Any elongation or de-prioritization of the Corporation's clinical trial recruitment and other activities could materially affect our business. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, it is currently resulting in significant disruption of global financial markets. This disruption, if sustained or recurrent, could make it more difficult for the Corporation to access capital if needed. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect the Corporation's business and the value of the Ortho Common Shares. The global COVID-19 pandemic continues to rapidly evolve. The ultimate impact of this pandemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on the Corporation's business, healthcare systems, or the global economy. These effects could have a material adverse impact on the Corporation's operations.

## **Limited Operating History**

The Corporation is a clinical-stage regenerative medicine Corporation, formed in 2015, with a limited operating history. Since inception we have devoted substantially all of our resources to the development of our regenerative medicine platform, the preclinical and clinical advancement of our product candidates, the creation, licensing and protection of related intellectual property rights and the provision of general and administrative support for these operations. We have not yet obtained regulatory approval for any product candidates in any jurisdiction or generated any revenues from product sales. If any of our future product candidates fails in clinical trials or preclinical development, or does not gain regulatory approval, or if our product candidates following regulatory approval, if any, do not achieve market acceptance, we may never become profitable or sustain profitability.

## **No History of Earnings**

We have incurred net losses since our inception and we expect to continue to incur substantial losses for the next several years, and we expect these losses to increase as we continue our development of and seek regulatory approval for our future product candidates. In addition, if we receive regulatory approval to market any of our future product candidates, we will incur additional losses as we scale our manufacturing operations and build an internal sales and marketing organization to commercialize any approved products. In addition, we expect our expenditures to increase as we add infrastructure and personnel to support our operations as a public Corporation. We anticipate that our net losses and accumulated deficit for the next several years will be significant as we conduct our planned operations.

Because of the numerous risks and uncertainties associated with regenerative medicine product development, we are unable to accurately predict the timing or amount of the development and clinical expenses or when, or if we will be able to achieve, or maintain, profitability. In addition, our expenses could increase if we are required by the FDA or comparable foreign regulatory authorities to perform preclinical or clinical studies or trials in addition to those currently expected, or if there are any delays in completing the technology transfer and manufacturing location transition of our raw material manufacturing process or completing our clinical trials or the development of our future product candidates. The amount of our future net losses will depend, in part, on the amount and timing of our expenses, our ability to generate revenue and our ability to raise additional capital. These net losses have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

## **Negative Cash Flow**

We have negative cash flow from operating activities. We anticipate that we will continue to have negative cash flow until such time that commercial production is achieved with a product candidate. To the extent that the Corporation has negative operating cash flows in future periods in excess of the amounts disclosed above in the use of proceeds, it may need to deploy a portion of its existing working capital to fund such negative cash flow.

## **Ability to Raise Additional Funds**

Developing regenerative medicine products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional capital in order to complete the clinical development of, create additional manufacturing capacity and to commercialize and to conduct the research and development and clinical and regulatory activities necessary to bring our product candidates to market. If the FDA or comparable foreign regulatory authorities require that we perform additional preclinical studies or clinical trials at any point or expand or extend our current trials, our expenses would further increase beyond what we currently expect, and the anticipated timing of any future clinical development activities and potential regulatory approvals will likely be delayed. Raising funds in the then-current economic environment may be difficult and additional funding may not be available on acceptable terms, or at all.

## **Development Risks**

The clinical development, commercialization and marketing of regenerative medicine products are at an early-stage, substantially research-oriented, and financially speculative. To date, very few companies have been successful in their efforts to develop and commercialize regenerative medicine products. In general, regenerative medicine products may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, potentially prohibitive costs or other characteristics that may prevent or limit their approval or commercial use. Furthermore, the number of people who may use cell- or tissue-based regenerative medicine therapies is difficult to forecast with accuracy. Our future success is dependent on the establishment of a large global market for regenerative medicine products and our ability to capture a share of this market with our product candidates.

Our development efforts with our regenerative medicine platform are susceptible to the same risks of failure inherent in the development and commercialization of product candidates based on new technologies. The novel

nature of regenerative medicine products creates significant challenges in the areas of product development and optimization, manufacturing, government regulation, third-party reimbursement and market acceptance.

### **Results of Early Clinical Trials**

Regenerative medicine product development has inherent risk. We or any of our future development partners will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective, with a favorable benefit-risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Regenerative medicine product development is a long, expensive and uncertain process, and delay or failure can occur at any stage of development, including after commencement of any of our clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Furthermore, our future trials will need to demonstrate sufficient safety and efficacy for approval by regulatory authorities in larger patient populations. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown

### **Product Liability**

The use of our future product candidates in clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by participants in clinical trials, consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates and any products for which we obtain marketing approval. There is a risk that our product candidates may induce adverse events, and that such adverse events may not be detected for a long period of time. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- increased costs due to related litigation;
- distraction of Management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale. <sup>(1)(2)</sup>

We carry product liability insurance that we believe is sufficient in light of our current clinical programs; however, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on regenerative medicine products or medical treatments that had unanticipated adverse effects. In addition, under some of our agreements with clinical trial sites, we are required to indemnify the sites and their personnel against product liability and other claims. A successful product liability claim or series of claims brought against us or any third parties whom we are required to indemnify could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

### **Dependence on key personnel**

Our success is dependent on certain key Management personnel, primarily its executives, which is key to the existence and continuity of the Corporation. Furthermore, competition for qualified employees among biotechnology industry companies is intense, particularly with regard to sales staff, and the loss of key personnel or inability to attract and retain the additional highly skilled employees required for the expansion of activities could adversely affect the Corporation's business.

### **Competitive market for the Corporation's products and services**

The biotechnology industry is highly competitive. Overall, many of our competitors in this industry is larger than the Corporation and might have greater financial and other resources, which could enable them to invest significant amounts of capital and other resources in their businesses, including expenditures for research and

development. If one of our current or future competitors develops innovative proprietary products, some of the Corporation's products could be rendered obsolete.

### **Protection of intellectual property**

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. There can be no assurance that our patent applications or those of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around, or invalidated by third parties. Even issued patents may later be found unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside Canada can be less extensive than those in Canada. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as laws in Canada. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside Canada, or from selling or importing products made using our inventions in and into Canada or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in Canada. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

### **Regulation**

In both domestic and foreign markets, the formulation, manufacturing, packaging, labelling, handling, distribution, import, export, licensing, sale and storage of the Corporation's products are affected by a body of laws, governmental regulations, administrative determinations, court decisions and similar constraints. Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of government in foreign jurisdictions. There can be no assurance that the Corporation is in compliance with all of these laws, regulations and other constraints. Failure by the Corporation to comply with these laws, regulations and other constraints or new laws, regulations or constraints could lead to the imposition of significant penalties or claims and could negatively impact the Corporation's business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead the Corporation to discontinue product sales and could have an adverse effect, resulting in significant loss of sales.

### **Requirements associated with being a reporting issuer and a publicly-listed company**

We are subject to the reporting requirements of Securities Laws and the other rules and regulations. We are working with our legal, accounting and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public reporting Corporation. These areas include corporate governance, corporate control, disclosure controls and procedures, and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas. Compliance with the various reporting and other requirements applicable to public reporting companies will require considerable time, attention of Management and financial resources. In addition, the changes we make may not be sufficient to allow us to satisfy our obligations as a public reporting corporation on a timely basis.

### **Dilution**

We will need to raise additional funding in order to complete the clinical development of, create additional manufacturing capacity and to commercialize products and to conduct the research and development and clinical and regulatory activities necessary to bring other product candidates to market. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In addition, if we seek funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us.

## No Dividends

We have never paid cash dividends on any of our share capital, and we currently intend to retain future earnings, if any, to fund the development and growth of our business. Therefore, you are not likely to receive any dividends on our Shares for the foreseeable future or at all. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our Shares will appreciate or even maintain the current price.

## Effective Control

As of January 31, 2021, our executive officers, directors, holders of more than ten percent of our Shares and their respective affiliates beneficially owned 25.6% of our outstanding share capital. Therefore, these shareholders will have the ability to influence us through their ownership position after this offering. These shareholders may be able to determine all matters requiring shareholder approval. For example, these shareholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our Shares that you may feel are in your best interest as one of our shareholders.

## Conflicts of interest

There exists the possibility for certain of our directors and officers to be in a position of conflict since most of them also work for affiliates of the Corporation.

## Risks of foreign exchange rate fluctuation

The Corporation is exposed to fluctuations of the Canadian dollar against certain other currencies because it publishes its financial statements in Canadian dollars, while a portion of its liabilities, revenues and costs could be denominated in other currencies. Exchange rates for currencies of the countries in which the Corporation operates may fluctuate in relation to the Canadian dollar, and such fluctuations may have a material adverse effect on our future earnings or assets when translating foreign currency into Canadian dollars. In general, the Corporation does not execute hedging transactions to reduce its exposure to foreign currency exchange rate risks. Accordingly, the Corporation may experience economic loss and a negative impact on earnings solely as a result of foreign exchange rate fluctuations, which include foreign currency devaluations against the Canadian dollar. The Corporation does not typically carry currency convertibility risk insurance.

## DIVIDENDS OR DISTRIBUTIONS

The Corporation's current intention is to re-invest future earnings to finance the growth of its business. Consequently, it does not intend to pay dividends in the foreseeable future. Any decision to pay cash dividends is left to the judgment of the Board and will depend on financial position, results of operations, capital requirements and such other factors as the Board shall deem relevant.

## DESCRIPTION OF SHARE CAPITAL

The Corporation's authorized share capital consists in an unlimited number of Shares without par value, of which 34,914,241 Shares are issued and outstanding as fully paid and non-assessable as of the date hereof. The holders of the Shares shall be entitled (i) to receive notice to all meetings of the shareholders of the Corporation; (ii) to one (1) vote for each Share held by them at all meetings of the holders of the Shares, (iii) to receive at all times, and from time to time, in the sole, absolute and unfettered discretion of the directors, to an unfixed non-cumulative dividend in any amount; and (iv) to participate in the distribution of the Corporation's property or assets upon liquidation, dissolution or wind-up.

## PRINCIPAL SECURITYHOLDERS

At the date of this AIF, no person beneficially owns, directly or indirectly, or exercises control or direction over, a number of Shares carrying more than 10% of the outstanding voting rights attached to the Shares, other than the following person:

Name	Number of Securities Held	Percentage of Total Issued and Outstanding Shares
Manitex Capital Inc. <sup>(1)</sup>	4,778,858	13.7%

(1) Mr. Saviuk is a Board Director and a significant shareholder of Manitex through Simcor Canada Holdings Inc.

## CONSOLIDATED CAPITALIZATION

The following table sets forth the capitalization of the Corporation as at January 31, 2021 based on the financial statements of the Corporation for the fiscal year ended January 31, 2021, and as of the date of this AIF.

Designation of Security	Authorized Amount	Outstanding as at January 31, 2021 (audited)	Outstanding as at the date of this AIF
Class "A" Shares	Unlimited	34,567,600	34,914,241
Share Options	10% of issued and outstanding Shares	2,746,000	2,871,000
Warrants	Unlimited	19,348,948	18,322,948
Convertible Debentures <sup>(1)</sup>	Unlimited	\$2,833,000	\$2,783,000

(1) Outstanding amounts represents the face value of convertible debentures.

## OPTIONS TO PURCHASE SECURITIES

### Option Plan

On November 20, 2015, the Board of the Corporation adopted a share option plan (the "**Option Plan**"). Further to a review of the Option Plan, the Board approved, on July 23, 2020, amendments to the Option Plan to stay in line with current market practices and make minor changes of a housekeeping nature. The Option Plan provides that the maximum number of Shares that may be reserved for issuance under outstanding share options shall be 10% of the Corporation's issued and outstanding Shares on a non-diluted basis, as constituted on the date of any grant of options under the Option Plan.

The purpose of the Option Plan is to allow the Corporation to grant options to directors, officers, employees and consultants, as additional compensation and as an opportunity to participate in the success of the Corporation. The granting of such options is intended to align the interests of such persons with that of the Corporation's shareholders.

Under the Option Plan, options will be exercisable over periods of up to 8 years as determined by the Board at the date of grant and are required to have an exercise price no less than the greater of (i) \$0.10 and (ii) the closing market price of the Shares on the trading day immediately preceding the day on which the Corporation announces the grant of options (or, if the grant is not announced, the date specified in an Option Agreement as the date on which the option is granted), less the applicable discount, if any, permitted by the policies of the CSE and approved by the Board. Pursuant to the Option Plan, the Board may from time to time authorize the issue of options to directors, senior officers, employees and consultants of the Corporation and its subsidiaries or employees of companies providing management or consulting services to the Corporation or its subsidiaries. The maximum number of Shares which may be issued pursuant to options previously granted and those granted under the Option Plan or any other stock option plan of the Corporation will be 10% of the issued and outstanding Shares at the time of the grant. In addition, the number of Shares which may be reserved for issuance to any one individual may not exceed (without the requisite disinterested shareholder approval) 5% of the issued Shares on a yearly basis or 2% if the optionee is engaged in investor relations activities or is a consultant. The Option Plan permits the Board to specify a vesting schedule in its discretion, subject to the CSE minimum vesting requirements, if any. Unless otherwise specified by the Board at the time of granting an option, and subject to the other limits on option grants set out in the Option Plan, all options granted under the Option Plan shall vest and become exercisable in full upon grant, except options granted to consultants performing investor relations activities, which options must vest in stages over twelve months with no more than one-quarter of the options vesting in any three-month period.

The Option Plan provides that if a change of control (as defined in the Option Plan) occurs, or if the Corporation is subject to a take-over bid, all Shares subject to options shall immediately become vested and may thereupon be exercised in whole or in part by the option holder. The Board may also accelerate the expiry date of outstanding options in connection with a take-over bid.

The Option Plan contains adjustment provisions with respect to outstanding options in cases of share reorganizations, special distributions and other corporation reorganizations including an arrangement or other transaction under which the business or assets of the Corporation become, collectively, the business and assets of two or more companies with the same shareholder group upon the distribution to the Corporation's

shareholders, or the exchange with the Corporation's shareholders, of securities of the Corporation or securities of another Corporation.

The Option Plan provides that on the death of an option holder, all vested options will expire at the earlier of 365 days after the date of death and the expiry date of such options. Where an optionee is terminated for cause, any outstanding options (whether vested or unvested) shall be cancelled as of the date of termination. If an optionee retires or voluntarily resigns or is otherwise terminated by the Corporation other than for cause, then all vested options held by such optionee will expire at the earlier of (i) the expiry date of such options and (ii) the date which is 90 days (30 days if the optionee was engaged in investor relations activities) after the optionee ceases its office, employment or engagement with the Corporation.

All outstanding options of the Corporation shall be governed by the Option Plan, including those issued prior to the implementation of the Option Plan; however, any vesting schedule imposed by the Corporation's previous stock option plan or stock option agreements in respect of any options issued prior to the implementation of the Option Plan will remain in full force and effect.

In accordance with good corporate governance practices and as recommended by *National Policy 51-201–Disclosure Standards*, the Corporation imposes black-out periods restricting the trading of its securities by directors, officers, employees and consultants during periods surrounding the release of annual and interim financial statements and at other times when deemed necessary by Management and the Board. In order to ensure that holders of outstanding options are not prejudiced by the imposition of such black-out periods, the Option Plan shall contain a provision to the effect that any outstanding options with an expiry date occurring during a Management imposed black-out period or within five trading days thereafter will be automatically extended to a date that is 10 trading days following the end of the black-out period.

As of the date of this AIF, the following table provides information about options to purchase Shares of the Corporation that are held by employees, officers and directors as a group, indicating the aggregate number of employees, officers and directors to whom the information applies:

Name	Designation and Number of Securities under option at the date hereof	Exercise Price (\$)	Expiry Date
Employees, Consultants, Scientific Advisory Board, as a group	25,000 Shares	\$0.40	July 12, 2021
	100,000 Shares	\$0.50	December 15, 2022
	150,000 Shares	\$0.36	June 19, 2024
	65,000 Shares	\$0.63	September 24, 2028
	75,000 Shares	\$0.60	October 29, 2028
	220,000 Shares	\$0.72	November 2, 2028
	15,000 Shares	\$0.71	December 17, 2028
Officers of the Corporation, as a group	100,000 Shares	\$0.50	June 23, 2021
	465,000 Shares	\$0.50	September 17, 2023
	500,000 Shares	\$0.36	June 19, 2024
	245,000 Shares	\$0.47	July 21, 2025
	15,000 Shares	\$0.71	December 17, 2028
Directors of the Corporation, as a group	350,000 Shares	\$0.50	May 17, 2022
	100,000 Shares	\$0.50	September 16, 2022
	100,000 Shares	\$0.36	June 19, 2024
	100,000 Shares	\$0.30	June 18, 2025
	96,000 Shares	\$0.71	December 17, 2028
	100,000 Shares	\$0.70	February 23, 2029
<b>Total</b>	<b>2,871,000 Shares under option</b>	-	-

## MARKET FOR SECURITIES

### Trading Price and Volume

The Ortho Shares are listed for trading on the CSE under the symbol "ORTH" since October 10, 2017 and on OTCQB under the symbol "ORTIF" since October 28, 2020. The following table sets forth the reported volume-weighted average closing prices and the trading volume on the CSE for the periods indicated:

Month	Volume-weighted average closing price (CDN\$)	Total Volume
May 2020	\$0.32	182,700
June 2020	\$0.35	135,400
July 2020	\$0.36	832,350
August 2020	\$0.40	640,219
September 2020	\$0.58	911,431
October 2020	\$0.59	1,213,770
November 2020	\$0.79	2,070,871
December 2020	\$0.68	2,295,941
January 2021	\$0.70	3,139,558
February 2021	\$0.75	3,223,751
March 2021	\$0.52	1,533,914
April 2021	\$0.41	699,355
May 2021 (May 1-May 30)	\$0.49	553,614

### Prior Sales

The following table summarizes the issuance of securities by the Corporation during the most recently completed financial year:

Date of Issue	Type of Security and Conversion Price
April 21, 2020	1,060 Unsecured Convertible Debentures Units (each a "Unit"), each Unit comprised of one 10% Unsecured Convertible Debentures in the principal amount of \$1,000 (each, a "Debenture") convertible at a \$0.30 price Share and 2,000 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 Share at an exercise price of \$0.50 ("Exercise Price"). If, during the twenty-four (24) months after the issuance of the Warrants, the Corporation's volume weighted average Common Share price for twenty (20) consecutive trading days equals or exceeds \$1.00, the Corporation may give notice to the Warrant holder that it must exercise its remaining Warrants within a period of 30 days from the date of receipt of the notice, failing which the Warrants will automatically expire. Both the Debentures and the Warrants have a maturity date of April 21, 2022.
August 24, 2020	Non-brokered private placement of units (the "Private Placement"). The Corporation issued 7,733,812 units (the "Units") at a purchase price of \$0.32 per Unit for total gross proceeds of \$2,474,820. Each Unit consists of one (1) common share of the Corporation (a "Share") and one (1) share purchase warrant of the Corporation (a "Warrant"). Each Warrant is exercisable into one (1) Share of the Corporation (a "Warrant Share") at the price of \$0.50 per Warrant Share for a period of 36 months from closing. In the event that the daily VWAP over any twenty (20) consecutive trading days is greater or equal to \$1.00, the Corporation may give notice to the Warrant holder, at any time after February 5, 2021, that all remaining Warrants must be exercised within a period of 30 days from the date of receipt of the notice, failing which the Warrants will automatically expire; and Non-brokered private placement of units for gross proceeds of approximately \$200,000 (the "Offering"). Each Unit will be priced at \$0.32 consisting of one (1) Share and one (1) Warrant. Each Warrant is exercisable into one (1) Share in the capital of the Corporation (a "Warrant Share") at the price of \$0.50 per Warrant Share for a period of 36 months from Closing. In the event that the daily VWAP over any twenty (20) consecutive trading days is greater or equal to \$1.00, the Corporation may give notice, at any time after February 5, 2021 to the Warrant holder that it must exercise its remaining Warrants within a period of 30-days from the date of receipt of the notice, failing which the Warrants will automatically expire.
September 2, 2020	\$137,600 additional non-brokered private placement of 430,000 units under the same terms and follows the closing of the private placement of units completed on August 24, 2020.
November 30, 2020	3,000 Secured Non-Convertible Debentures Units (each a "Unit"), each Unit comprised of a 3-year 10% Secured Non-Convertible Debenture in the principal amount of \$1,000 and 500 share purchase Warrants (a "Warrant") of the Corporation. Each Warrant will be exercisable for one Share (a "Warrant Share") at the price of \$0.75 per Warrant Share and will expire 36 months after date of issuance.

## DIRECTORS AND EXECUTIVE OFFICERS

### Current Directors

The following table sets forth the name, province or state, and country of residence of each of the directors of the Corporation as at May 31, 2021, as well as their position with the Corporation, as applicable, or their principal occupation, as well as the year in which they became directors of the Corporation. Each director's term of office will expire at the next annual general meeting of the Corporation.

Name, Province and Country of Residence	Director Since	Principal Occupation During the Past Five Years	Number and Percentage of Shares <sup>(1)</sup>
Michael C. Atkin <sup>(3)</sup> Quebec, Canada	June 18, 2020	Chairman of the Corporation President of Syzent Partners Ltd.	65,000 (0.2%)
Pierre Laurin <sup>(2) (3)</sup> Quebec, Canada	June 19, 2019	President and CEO of InvHealth Capital Inc. and Ingenew Pharma Inc.	368,500 (1.1%)
Claude LeDuc Quebec, Canada	June 19, 2019	Currently President and CEO of the Corporation, President & CEO of MRM Proteomics Inc., President & COO of Axcellon Dermacare Inc.	293,013 (0.8%)
Dr. Brent Norton Ontario, Canada	July 26, 2019	Venture Partner at Lumira Capital, Past Executive Chairman and CEO of Ortho	322,500 (0.9%)
Patrick T. O'Donnell Massachusetts, USA	February 24, 2021	President and CEO of HD Life Sciences	nil
Steve Saviuk <sup>(2) (4)</sup> Quebec, Canada	February 5, 2015	President and CEO of Manitex President and CEO of Valeo Pharma Inc.	5,013,204 (14.4%)
Tom E.S. Wright <sup>(2) (3)</sup> Ontario, Canada	September 26, 2017	Founder and President of S10 Management Group Executive Vice-President and General Manager at Ultimate Fighting Championship (Canada, Australia and New Zealand)	100,000 (0.3%)

(1) Shares Beneficially Owned, or Controlled Directly or Indirectly

(2) Member of the Audit Committee (refer to "Audit Committee")

(3) Member of the Compensation and HR Committee

(4) Mr. Saviuk holds his Shares directly (87,265 Shares) and also through Manitex (4,408,726 Shares) and Simcor Canada Holdings Inc., (517,213 Shares), companies over which he has control or effective control.

### Current Officers

The following table sets forth the name, province and country of residence and position within the Corporation of each person who is an executive officer as of the date hereof.

Name, Province and Country of Residence	Position with the Corporation	Officer since	Other Principal Occupation During the Past Five Years	Number and Percentage of Shares <sup>(1)</sup>
Claude LeDuc Quebec, Canada	President and CEO	June 17, 2019	President & CEO of MRM Proteomics Inc., President & COO of Axcellon Dermacare Inc.	293,013 (0.8%)
Luc Mainville Quebec, Canada	Senior VP & CFO	September 18, 2018	Chairman of Zucara Therapeutics Inc. Interim CEO at Acerus Pharmaceuticals Executive VP at Cardiome Pharma Corp.	1,148,500 (3.3%)
Guy Paul Allard Quebec, Canada	VP Legal Affairs & Corporate Secretary	June 23, 2016	VP Legal Affairs & Corporate Secretary of Valeo Pharma Inc. and of Manitex Counsel, Dentons Canada LLP	113,475 (0.3%)
Michael Buschmann Virginia, USA	Chief Scientific Officer	February 5, 2015	Chair, Dept. of Bioengineering, Volgenau School of Engineering, George Mason University (Virginia, USA) Professor at Polytechnique (1994-2017)	2,090,222 (6%)

(1) Shares beneficially owned, or controlled, directly or indirectly

(2) Luc Mainville holds his Shares directly (906,000 Shares) and also indirectly through his spouse (242,500 Shares).

### **Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

Except as disclosed below, no director or executive officer or promoter of the Corporation is, at the date of this AIF, or has been, within the 10 years prior to the date this AIF, a director, chief executive officer or chief financial officer of any issuer (including the Corporation) that:

- (a) was subject to an Order (as defined below) that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
- (b) was subject to an Order that was issued after the director ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

“**Order**” means a cease trade order or similar order or an order that denied an issuer access to any statutory exemption under securities legislation that was in effect for a period of more than 30 consecutive days.

In addition, except as disclosed below, no director or executive officer or promoter of the Corporation or shareholder holding sufficient number of securities of the Corporation to affect materially the control of the Corporation:

- (a) is, at the date this AIF, or has been within the 10 years before the date hereof, a director or executive officer of any issuer (including the Corporation) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangements or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets;
- (b) has, within the 10 years before the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of that person; or
- (c) has been subject to:
  - (i) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
  - (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

Steve Saviuk was a Director and the CFO of Cabia Goldhills Inc. (CGH.V) (“Cabia”) until October 28, 2015. On April 5, 2013 a cease trade order, which is still in effect, was issued by the *Autorité des marchés financiers* against Cabia for failing to file its annual financial statements within the required time period. In June 2017, Cabia filed for bankruptcy.

Tom E.S. Wright is a director of Muskoka Grown Ltd., a private Corporation that filed a Notice of Intent to restructure its operations under the *Bankruptcy and Insolvency Act* in May 2020.

### **Conflicts of Interest**

The directors of the Corporation are required by law to act honestly and in good faith with a view to the best interest of the Corporation and to disclose any interests which they may have in any project or opportunity of the Corporation. If a conflict of interest arises at a meeting of the Board, any director in a conflict is required to disclose his interest and abstain from voting on such matter.

To the best of the Corporation’s knowledge, there are no known existing or potential conflicts of interest among the Corporation, its promoters, directors, officers or other members of Management of the Corporation as a result of their outside business interests except that certain of the directors, officers, promoters and other members of Management of Ortho serve as directors, officers, promoters and members of management of other private and public companies.

The directors and officers of the Corporation are aware of the existence of laws governing accountability of directors and officers for corporate opportunity and requiring disclosures by directors of conflicts of interest and the Corporation will rely upon such laws in respect of any directors’ and officers’ conflicts of interest or in respect of any breaches of duty by any of its directors or officers. Such directors or officers, in accordance with the *Canada Business Corporations Act* are required to disclose all such conflicts and are expected to govern themselves in respect thereof to the best of their ability in accordance with the obligations imposed upon them by law.

## AUDIT COMMITTEE

### (a) Audit Committee Charter

The Corporation's Board and Audit Committee have adopted an audit committee charter in accordance with National Instrument 52-110- *Audit Committees* ("NI 52-110"). The Corporation's audit committee charter is attached to this AIF as Schedule A.

### (b) Composition of the Audit Committee

The members of the audit committee are Pierre Laurin, Steve Saviuk and Tom E.S. Wright. Mr. Laurin and Mr. Wright are considered to be "independent" within the meaning of NI 52-110. Each member of the committee is financially literate within the meaning of NI 52-110 - *Audit Committees* and is able to assess the general application of the accounting principles in connection with the preparation of financial statements and the accounting for estimates, accruals and reserves as well as having an understanding of internal controls and procedures for financial reporting.

Mr. Laurin was President and CEO of a public company for over 25 years and has extensive experience in analyzing financial statements.

Mr. Saviuk has a degree in commerce and started his career in accounting at KPMG. In addition, Mr. Saviuk has extensive experience in analyzing financial statements as director and officer of various public companies.

Mr. Wright is the chair of the audit committee. Mr. Wright holds a Master's in Business Administration and is also a graduate of the Institute of Corporate Directors, Directors Education Program.

### Audit Committee Oversight

The Audit Committee is directly responsible for the appointment (subject to shareholder ratification), compensation and oversight of the independent auditor of the Corporation, who reports directly to the Audit Committee. At no time since the commencement of the Corporation's most recently completed financial period was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board of Directors.

### Pre-Approval Policies and Procedures

The Audit Committee has not adopted specific policies and procedures for the engagement of non audit services. However, the Charter of the Audit Committee provides that the provision of any non audit services must first be considered by the Audit Committee.

### Fees paid to External Auditor

The table below sets out the fees incurred by the Corporation for the fiscal year ending on January 31, 2021, and 2020.

	2020	2021
Audit Fees <sup>(1)</sup>	\$72,000	\$65,000
Tax Fees <sup>(2)</sup>	\$6,100	\$6,300
Other Audit-Related Fees <sup>(3)</sup>	\$10,000	\$5,000
<b>Total</b>	<b>\$88,100</b>	<b>\$76,300</b>

(1) Aggregate fees billed by the Corporation's external auditor for audit services.

(2) Aggregate fees billed by the Corporation's external auditor for professional services rendered for tax compliance, tax advice and tax planning.

(3) Aggregate fees billed by the Corporation's external auditor and not included above.

### Reliance on Exemption

The Corporation is relying on the exemption contained in Section 6.1 of NI 52-110 that provides that the Corporation, as a venture issuer, is not required to comply with Part 5 (Reporting Obligations) of NI 52-110.

## APPOINTMENT OF AUDITORS AND AUDITORS' REMUNERATION

The Audit Committee is directly responsible for the appointment (subject to shareholder ratification), compensation and oversight of the independent auditor of the Corporation, who reports directly to the Audit Committee. Ernst & Young LLP became the Corporation's auditor on September 12, 2017 following their appointment by the Board.

## **LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

The Corporation currently has no material legal proceedings and regulatory actions pending.

## **INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

To the knowledge of the Board, as of the date of this AIF, except as described under “Principal Shareholders” no person or Corporation beneficially owns, controls or directs, directly or indirectly, Shares carrying more than 10% of the voting rights attached to the Shares.

To the knowledge of the Board, as of the date of this AIF except for the agreements described under “Description of the Business” and for the other relationships described in this AIF, no director nor officer and no person or Corporation beneficially owning, controlling or directing, directly or indirectly, Shares carrying more than 10% of the voting rights attached to Shares, nor any associates or affiliates of the foregoing, has any material interest in any transactions involving the Corporation.

## **TRANSFER AGENT AND REGISTRAR**

The registrar and transfer agent of the Corporation is Computershare Investor Services Inc., at its office in Montréal, Quebec, Canada.

## **MATERIAL CONTRACTS**

Except for contracts entered into the ordinary course of business, there are no other contracts entered into by Ortho since the last financial year, or before the beginning of the last financial year, which may be regarded as material.

## **INTERESTS OF EXPERTS**

Ernst & Young LLP, the external auditor of the Corporation, advised the Corporation that it is independent of the Corporation in accordance with the Rules of Professional Conduct of the *Ordre des CPA du Québec*.

## **ADDITIONAL INFORMATION**

Additional information relating to Ortho may be found under the Corporation’s profile on SEDAR at [www.sedar.com](http://www.sedar.com) and the Corporation’s website [www.orthorti.com](http://www.orthorti.com). Further information with respect to the Corporation, including directors’ and officers’ remuneration and indebtedness, principal holders of securities of the Corporation and securities authorized for issuance under equity compensation plans is contained in the Management Information Circular of the Corporation for the next shareholders meeting to be held on July 21, 2021.

## **SCHEDULE A**

### **ORTHO REGENERATIVE TECHNOLOGIES INC. (the "Corporation")**

#### **AUDIT COMMITTEE CHARTER**

##### **PURPOSE**

The Audit Committee is appointed by the Board to assist in fulfilling its oversight responsibilities of the Corporation. In so doing, the Committee provides an avenue of communication among the independent auditors, Management, and the Board. The Committee's primary duties and responsibilities are to gain reasonable assurance of the following:

- That the Corporation complies with the applicable laws, regulations, rules, policies and other requirements of governments, regulatory agencies and stock exchanges relating to financial reporting and disclosure;
- The independence and satisfactory performance of duties by the Corporation's independent auditors;
- That the accounting principles, significant judgments and disclosures that underlie or are incorporated in the Corporation's financial statements are the most appropriate in the prevailing circumstances;
- That the Corporation's quarterly and annual financial statements present fairly the Corporation's financial position and performance in accordance with generally accepted accounting principles; and
- That appropriate information concerning the financial position and performance of the Corporation is disseminated to the public in a timely manner.

##### **COMPOSITION AND OPERATING PROCEDURES**

Audit Committee members shall meet the requirements of the exchange upon which the Corporation is listed as well as all government regulatory bodies. The Committee shall be comprised of at least three Directors as determined by the Board, a majority of whom shall be independent non-executive Directors, free from any relationship that would interfere with the exercise of his independent judgment. All members of the Committee shall be financially literate.

The Committee members shall be appointed by the Board. The Board shall designate the Chair of the Committee annually.

The Committee shall meet at least four times annually, or more frequently as circumstances dictate. Quorum shall be a majority of the members.

The Committee, in consultation with Management and the independent auditors, shall develop and participate in a process for review of important financial topics that have the potential to impact the Corporation's financial policies and disclosures.

The Committee shall annually review, discuss and assess its own performance. In addition, the Committee shall periodically review its role and responsibilities.

The Committee expects that, in discharging their responsibilities to the shareholders, the independent auditors shall be accountable to the Board through the Committee. The independent auditors shall report all material issues or potentially material issues to the Committee.

##### **RESPONSIBILITIES AND DUTIES**

###### **A. Financial Accounting and Reporting Process**

- Review the Corporation's annual audited financial statements and the Corporation's Management Discussion and Analysis prior to filing or distribution, and report its findings for

approval to the Board. Review should include discussion with Management and independent auditors of significant issues regarding accounting principles, practices and judgments.

- Review the Corporation's quarterly unaudited financial statements and the Corporation's Management Discussion and Analysis prior to filing or distribution, and report its findings for approval to the Board.
- Ensure that adequate procedures are in place for the review of the Corporation's disclosure of financial information extracted or derived from the Corporation's financial statements, and periodically assess the adequacy of those procedures.
- In consultation with Management and the independent auditors, consider the integrity of the Corporation's financial reporting processes and controls. Review significant findings prepared by the independent auditors together with Management's responses.
- Review with Management and the independent auditors the appropriateness of the Corporation's accounting policies, disclosures, key estimates and judgments, including changes or alternatives thereto and to obtain reasonable assurance that they are in compliance with IFRS, and report thereon to the Board.
- Establish procedures for the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls, or auditing matters, and the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters.

#### B. Independent Auditors

- The independent auditors are ultimately accountable to the Committee and the Board. The Committee shall review the independence and performance of the auditors and annually recommend to the Board the appointment of the independent auditors or approve any discharge of auditors when circumstances warrant.
- Assume direct responsibility for overseeing the work of the independent auditors engaged to prepare or issue an audit report or perform other audit, review or attest services for the Corporation, including the resolution of disagreements between Management and the independent auditors regarding financial reporting.
- Evaluate and recommend to the Board the independent auditors to be nominated to prepare or issue an audit report or perform other audit, review or attest services for the Corporation, and the compensation of the independent auditors.
- Pre-approve all non-audit services to be provided to the Corporation by its independent auditors.
- Consider the independent auditors' judgments about the quality and appropriateness of the Corporation's accounting principles as applied in its financial reporting.