

# Ortho Regenerative Technologies Inc.



## Management's Discussion and Analysis for the three and six-month periods ended July 31, 2021

*(In thousands of Canadian dollars, except for units, share and per share amounts)*

### MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL REPORTING

This Management's Discussion and Analysis ("MD&A") for Ortho Regenerative Technologies Inc. (the "Corporation" or "ORT") provides an overview of the Corporation's operations, performance and financial results for the second quarter of fiscal year 2022, ended on July 31, 2021 and compares those of the same period in fiscal year 2021. This MD&A is the responsibility of management and has been reviewed and approved by its Board of Directors. The Board of Directors is responsible for ensuring that management fulfills its responsibilities for financial reporting and is ultimately responsible for reviewing and approving the MD&A. The Board of Directors carries out this responsibility principally through its Audit Committee. The Audit Committee is appointed by the Board of Directors and is comprised of financially literate directors, majority of which are independent. This report was reviewed by the Corporation's Audit Committee and approved by ORT's Board of Directors on September 30, 2021. This document should be read in conjunction with the unaudited financial statements and notes thereto for the fiscal quarter ended on July 31, 2021 which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). Unless otherwise noted, all amounts are presented in thousands of Canadian dollars, except for share and per share amounts. Further information about ORT, including the Annual Information Form, is available online on SEDAR at [www.sedar.com](http://www.sedar.com).

### Going concern

This MD&A has been prepared on a going-concern basis, which implies that the Corporation will continue realizing its assets and discharging liabilities in the normal course of business for the foreseeable future. As reflected in the annual audited financial statements, the Corporation is still a clinical stage R&D company and has not yet achieved profitability. During the quarter ended on July 31, 2021, the Corporation incurred a net loss of \$0.9 million, and used cash in operations of \$1.6 million for the first six months of fiscal year 2022. Considering the above, and despite the working capital surplus of \$0.8 million as at July 31, 2021, the Corporation's performance raises significant doubt about its ability to continue as a going concern.

Accordingly, the ability of the Corporation to realize the carrying value of its assets and continue operations as a going concern is dependent upon its ability to obtain additional financing and ultimately on generating future profitable operations. Management anticipates that the continued advancement of its lead Ortho-R program will facilitate securing additional funds from existing and new investors. There is no assurance that any fund-raising initiatives will be successful. Factors within and outside the Corporation's control could have a significant bearing on its ability to obtain additional financing. The financial statements as at and for the quarter and year-to-date period ended July 31, 2021 do not include any adjustments related to the carrying values and classifications of assets and liabilities that would be necessary should the Corporation be unable to continue as a going concern.

### Covid-19 pandemic

The outbreak of a novel strain of coronavirus, identified as "COVID-19", was declared a global pandemic by the World Health Organization on March 11, 2020 and is still adversely affecting the global economy despite the efforts by local governments to vaccinate their populations and reduce the economic adverse effects of COVID-19. In response, many countries have required entities to limit or suspend business operations and implemented travel restrictions and quarantine measures. Some non-essential activities were canceled or delayed due to COVID-19. These measures have disrupted the activities of many entities and have led to significant volatility in the global markets. The Corporation continues to monitor and actively manage the developing impacts from COVID-19, including but not limited to, the effect on the Corporation's clinical development phases, potential future effects on its assets, cash flow and liquidity, and will continue to assess impacts to the Corporation's operations, going concern assumption, and the value of assets and liabilities reported in its financial statements. Management believes that the progress made in the US in fighting the pandemic will trigger an acceleration of the elective orthopedic surgeries which have been subject to delays over the last year. Elective surgeries levels are key to ensure enrollment in our US Phase I/II clinical trial on rotator cuff tear repair.

### Non-IFRS Financial Measures

This MD&A refers to certain non-IFRS measures. Management uses these non-IFRS financial measures for purposes of comparison to prior periods and development of future projections and earnings growth prospects. This information is also used by management to measure the results of ongoing operations and in analyzing our business performance and trends. These measures are not recognized measures under IFRS, do not have a standardized meaning prescribed by IFRS and are therefore unlikely to be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement those IFRS measures by providing further understanding of our results of operations from management's perspective. Accordingly, they should not be considered in isolation nor as a substitute for analysis of our financial information reported under IFRS. We use a non-IFRS measure, "EBITDA", to provide supplemental measures of our operating performance and thus highlight trends in our core business that may not otherwise be apparent when relying solely on IFRS financial measures. EBITDA is defined as net income (loss) before (i) provision for (recovery of) income taxes; (ii) interest (income) expense and other financing costs; (iii) depreciation; and (iv) amortization of intangible assets.

### Cautionary note regarding forward-looking statements

This MD&A may contain some forward-looking information as defined under applicable Canadian securities laws. Forward looking information can generally be identified using forward-looking terminology such as "may", "anticipate", "expect", "intend", "estimate", "continue" or similar terminology. Forward looking information is subject to various known and unknown risks and uncertainties, many of

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which are beyond the ability of the Corporation to control or predict, that may cause the Corporation’s actual results or performance to be materially different from actual results and are developed based on assumptions about such risks and other factors set out herein.

**GLOSSARY TERMS**

**Calendar & Financial**

CDU	Convertible Debenture Units
EBITDA (L)	EBITDA Loss
FY-20	Fiscal Year ended January 31, 2020
FY-21	Fiscal Year ended July 31, 2021
FY-22	Current Fiscal Year ending January 31, 2022
G&A	General and Administrative
IR	Investors Relations
ITC	Investment tax credits
NCDUs	Non-Convertible Debenture Units
Q2-22	Second quarter FY-22
Q1-22	First quarter FY-22
Q4-21	Fourth quarter FY-21
Q3-21	Third quarter FY-21
Q2-21	Second quarter FY-21
Q1-21	First quarter FY-21
Q4-20	Fourth quarter FY-20
Q3-20	Third quarter FY-20
SR&ED	Scientific Research and Experimental Development Expenses
R&D	Research and Development
YTD	Year to date
YE-21	Year-end 2021 – January 31, 2021
W/C	Working Capital, defined as short-term assets less short-term liabilities

**Corporate & Operations**

API	Active Pharmaceutical Ingredient
CMC	Chemistry Manufacturing and Controls
cGMP	current Good Manufacturing Practice
CMO	Contract Manufacturing Organization
CSE	Canadian Securities Exchange
FDA	US Food and Drug Administration
IND	Investigational New Drug application with the FDA
MCRA	MCRA, LLC, a US based orthopedic specialty CRO
MRI	Magnetic Resonance Imaging
MTA	Material Transfer Agreement
ORT	Ortho Regenerative Technologies Inc.
ORTHO-C	Proprietary biopolymer for Articular Cartilage repair
ORTHO-M	Proprietary biopolymer for Proprietary Biopolymer for Meniscus repair
ORTHO-R	Proprietary biopolymer for Rotator cuff repair
ORTHO-V	Proprietary biopolymer for Osteoarthritis healing
OTCQB	US over-the-counter venture trading market
Polytechnique	Ecole Polytechnique de Montreal
PRP	Platelet-rich plasma
Pre-RFD	Pre-Request for Designation

**OVERVIEW OF THE BUSINESS AND BUSINESS STRATEGY**

ORT has been incorporated under the Canada Business Corporations Act. The Corporation’s head office, principal address and registered office is located at 16667 Hymus Blvd., Kirkland, Quebec, Canada. The Corporation’s shares are publicly traded on the CSE under the symbol “*ORTH*”, as well as on the United States OTCQB market under the symbol “*ORTIF*”.

The Corporation is an emerging Orthopaedic and Sports Medicine biologics company dedicated to the development of novel therapeutic soft tissue repair technologies to dramatically improve the success rate of orthopaedic 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, 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 at Polytechnique by senior researchers at the Biomaterials and Cartilage Laboratory and are still actively involved in the day-to-day development of ORT’s pipeline.

ORT is the owner of 4 patent families. Our patent portfolio includes the following:

- Patent Family No.1: Clot-activated polymer composition for repairing the tissue of the subject, where the polymer composition adheres to the tissue and promotes cell proliferation, comprising platelet-rich plasma (PRP), a biopolymer, a salt and a clot activator.
- Patent Family No.2: Novel formulation of physiological biopolymer-inorganic salt solution/blood mixtures for tissue repair. *This patent family was abandoned on November 9, 2019.* The company’s Freeze-Dried platform patents (family 3-4, covers all applications found in the Patent Family No.2 plus many other claims, such as faster coagulation onset time, easier use for the clinicians and a much longer commercially viable shelf life.
- Patent Family No.3: Freeze-dried polymer compositions for mixing with platelet rich plasma to form implants for tissue repair or compositions for therapeutic intra-articular injection.
- Patent Family No.4: Freeze-dried biopolymer scaffolds that form a hydrated microparticle dispersion after contact with blood or blood-derived fluids and stimulate anabolic wound repair processes, including angiogenesis, cell chemotaxis, tissue remodeling, and extracellular matrix.

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**Development Pipeline**

ORT’s lead program is ORTHO-R, a Drug-PRP Biologic Implant, specifically designed to guide and accelerate the repair of various musculoskeletal conditions. The Corporation is aiming to assess the clinical safety and efficacy of Ortho-R, initially for Rotator Cuff repair. Ortho-R can also be used to accelerate the healing of other soft tissues such as ligaments and meniscus (see Ortho-M).

ORT’s pipeline includes four active R&D projects:

Program	Development Stage	Indication	Details
<u><b>ORTHO-R</b></u>	Clinical Phase I/II	Rotator Cuff	<p>Ortho-R is designated as a Drug/Biologic combination product by the FDA Office for Combination Products. The jurisdictional assignment for ORTHO-R is the Center for Biologics Evaluation and Research (CBER). A US IND has been filed on April 6<sup>th</sup>, 2021, with the FDA to obtain approval to initiate a 78 patient Phase I/II clinical trial to test Ortho-R in the repair of rotator cuff tears as an adjunct to standard of care surgery, versus standard of care surgery alone. (See “Regulatory and Clinical update – Ortho-R for Rotator Cuff Repair” section below for details of our ongoing interaction with FDA related to our IND application).</p> <p>After clearance of our IND by the FDA and clinical site’s Ethical Review Board’s approval, enrollment will start at clinical sites. Eight clinical sites have already been qualified, budget negotiations have started and 4 more are undergoing the same processes, with the goal to secure 10 sites or more total. Patient enrollment is expected to start within 4-6 weeks of our IND approval by the FDA, and to be completed 6 to 8 months after, depending on sites’ enrolment rate.</p>
<u><b>ORTHO-M</b></u>	Pre-Clinical	Meniscus	<p>Testing the efficacy of ORTHO-M/PRP Drug-Biologic Implant formulation, for meniscus repair. Efficacy of our product has already been demonstrated in a animal proof of concept study. Our contracted research veterinarian expert, with the help of a major arthroscopic instrumentation company, have recently completed the development of surgical instruments tools, suitable to the sheep preclinical model. The next steps are to validate our model in large animal pilot and pivotal studies, starting in FY-22. Human clinical trials would then follow.</p>
<u><b>ORTHO-C</b></u>	Pre-Clinical	Cartilage repair	<p>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.</p>
<u><b>ORTHO-V</b></u>	Feasibility	Osteoarthritis	<p>Feasibility research on a freeze-dried biopolymer formulation combined with autologous biologics, tailored for intra-articular injections to provide the combined visco-biologics supplementation of articular joints and potentially gain disease modification outcomes in applications such as Osteoarthritis.</p>

Considering the significant bioactivity and residency of our proprietary biopolymer – PRP implants, ORT continues to assess its potential for therapeutic uses outside of the soft tissue repair market.

**Ortho-R for Rotator Cuff repair**

ORTHO-R is a patent-protected freeze-dried formulation of a biopolymer, a lyoprotectant and a clot activator. ORTHO-R is solubilized in platelet-rich plasma (“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 following 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 as an adjunct to standard of care suturing techniques produced promising histological findings in small and large animal models, which is expected to translate to faster and superior rotator cuff repair in 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.

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#### Preclinical:

Earlier in Q2-22, 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)

#### Manufacturing & CMC:

Our cGMP clinical lot production has been successfully completed during Q2-22 and such material will be used in our upcoming Phase I/II human clinical trial for testing ORTHO-R in rotator cuff tear repair. The manufacturing batch will also provide sufficient material to support our Meniscus tear repair preclinical program, expected to be initiated shortly after the commencement of our Phase I/II Rotator cuff repair trial, in FY Q4-22.

#### Regulatory & Clinical:

In Q2-21, we received from the US FDA Office of Combination Products, the ORTHO-R product designation as a Drug/Biologics combination product. ORTHO-R has physicochemical interacting actions on various cell types and other PRP components, therefore supporting a Drug/Biologic combination product. The ORTHO-R reconstituted in PRP Drug/biologic implant is delivered through accessory Devices. 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 following summarizes our interaction with the FDA with respect to the filing and ongoing review of the ORTHO-R Investigational New Drug (IND) application:

- Our Investigational New Drug (IND) application to the FDA was submitted on April 6, 2021.
- On June 4, 2021, the Corporation received a clinical hold letter from the FDA relating to its IND application. FDA requested five additional clarification and requests, related to Chemistry, Manufacturing, and Control ("CMC").
- On July 19, 2021, The Corporation provided a formal response to the FDA's clinical hold letter, to address the requested CMC-related data and characterization information.
- On August 17, 2021, The Company received, a "Second Clinical Hold" letter from the FDA. In our July response, the three most complex addressed issues were accepted by the FDA. The second FDA Clinical Hold letter referred to further clarification on CMC Elemental impurity testing method and a request to use a different testing method for small molecule impurity testing.
- The Company worked with its U.S. CMC testing experts on the new FDA requests related to advanced methods of elemental and small-molecule impurities characterization testing used in the CMC processes. On September 2, 2021, The Company responded to the Second Clinical Hold letter first request, by submitting additional clarification on elemental impurities identification and quantification testing methods to the FDA. The Company addressed the second request, by accepting the FDA's recommendation to use GC-LC-MS for small molecule impurities testing instead of HCLP-PAD used by our CMC manufacturer. This new testing method is ongoing, and results will be available within a few weeks. The Company is confident that its response to the Second Clinical Hold letter will address both the requirements for clarifications and address the deficiencies to the complete and final satisfaction of the FDA.
- Concurrently as a proactive step, the Company has requested a type A meeting with the FDA, should the FDA still request further clarification on the proposed elemental impurities testing method. This meeting would involve the participation of our U.S. CMC testing experts that use the same IPC-MS testing method for their other Biopharma industry clients for drugs and biologics when submitting INDs to the FDA. The type A meeting has been scheduled for **October 5, 2021**.

While waiting for our IND clearance, we continue working on our Phase I/II clinical trial preparation activities to ensure we minimize the impact on our overall timelines. Current activities focus mainly on surgery and study protocol, patients' assessment EDC system, MRI procedure protocol and systems qualification and clinical sites considerations and qualifications.

So far, eight sites have already been qualified, budget negotiation has started and Clinical Review Board (CRB) applications have started to be submitted. Four other U.S. sites are still being qualified, with the goal to reach a minimum of 10 sites to participate in our Rotator Cuff Tear repair clinical trial.

Assuming clearance of our IND application by the FDA shortly after the October 5, 2021 Type A meeting, patients' enrollment would be expected to start by the end of calendar year 2021, immediately after Clinical Review Boards (CRB) approvals from the various U.S. clinical testing centers involved in our Phase I/II study.

Over the past quarters, the Corporation has tried to mitigate the impact of the COVID-19 pandemic as much as possible. We believe that the significant progress made in the US fighting the pandemic will favor a substantial increase in elective rotator cuff repair surgeries across

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the United States in 2021 and 2022 compared to 2020. We feel this may help the investigational sites, in their patient’s screening, recruitment and inclusion selection process, to participate in our U.S. Phase I/II clinical trial.

The following tables presents a summary of the past and projected milestones based on calendar quarters/years for the 2019-2023 period, including progress as compared to prior MD&A reporting:

Past and Projected Milestones	Calendar Year 2019-2023	Calendar Quarters/Years								
		2019	2020	Q1-21	Q2-21	Q3-21	Q4-21	H1-22	H2-22	H1-23
<b>Corporate / Strategic</b>	Licensing Agreement - Ingenew Pharma		☑							
<b>Rotator Cuff Repair Program (Ortho-R)</b>	CMC Manufacturing		➔	☑						
	6-month pivotal animal trial		☑							
<b>US-FDA IND</b>	Pre-IND Meeting - FDA	☑								
	IND filing				☑					
	IND approval				●	■	■			
<b>US Phase I/II Clinical trial</b>	CRO Selection	☑								
	Protocol completion		☑							
	Lead Investigator selection		☑							
	Study sites selection					☑				no change from prior MD&A
	Clinical sites qualification			➔	☐	■				
	Clinical sites training						➔	■		
	Phase I/II trial activities			➔						
	First patient enrolled				☐	■				
	50% enrolment completed							■		no change from prior MD&A
	enrolment completed							■		no change from prior MD&A
	12-mth patient follow up completed								■	no change from prior MD&A
	Study results								■	no change from prior MD&A
<b>Meniscus Program (Ortho-M)</b>	Program to be re-started after Completion of Rotator Cuff trial enrolment									Program on hold

➔ Initiation  
 ■ Current Target Completion  
 ☐ previous target last quarter  
 ☑ Completed  
 ● On-Hold

## Second Quarter 2022 CORPORATE HIGHLIGHTS

### ORTHO-R Program

- On June 4, 2021, the Corporation announced that it had received a clinical hold letter from the FDA related to its IND application to begin a phase I/II clinical trial for ORTHO-R. The FDA requested additional CMC related information. The Company is confident in its ability to address and provide the FDA with the required information and testing data within four to six weeks from reception of the letter.
- On July 20, 2021, the Corporation announced that it had provided and filed all requested CMC-related data and characterization information in a formal response to the U.S. Food and Drug Administration (FDA) aiming to address the clinical hold on its Investigational New Drug (IND) application for ORTHO-R. ORTHO-R is a drug/biologic combination product candidate used as an adjunct to improve the success rate of standard of care surgery in rotator cuff tear repair.
- On August 20, 2021, the Corporation announced that the U.S. Food and Drug Administration (“FDA”) had extended the clinical hold on the Company’s Investigational New Drug (“IND”) application to proceed with the initiation of a U.S. Phase I/II clinical trial of ORTHO-R in rotator cuff tear repair. The FDA has accepted the three most complex requested additional information submitted in response to the initial clinical hold letter received in early June 2021. The FDA has however requested supplemental clarifications on two advanced methods of characterization of impurities

### Financing and Other Corporate Highlights

- On June 15, 2021, the Corporation announced the appointment of Messrs. Howard Walthall and Tim Cunningham to its Board of Directors. Concurrent with their appointments, each of them received 100,000 incentive share options at an exercise price of \$0.36 per share and expiring June 15, 2029. Vesting of the options will take place as per the Corporation’s plan. Howard P. Walthall is a seasoned life sciences executive whose multi-faceted experience includes cellular biologics, tissue engineering, medical devices and allografts. He has an extensive background in regenerative medicine, orthopedics and advanced wound care. Howard has overseen multiple highly successful product development projects and new product launches. Mr. Walthall is currently the President, Founder and CEO of Lumiheal Therapeutics Inc., a company developing and commercializing a patented technology that uses fluorescent light energy to heal chronic and acute wounds, burns, and surgical incisions. Previously, Mr. Walthall was the Executive Vice President Strategy and Market Development for Organogenesis where he led sales, marketing and R&D for the Surgical and Sports Medicine (SSM) product lines. He also led the overall Strategy and Business Development functions for Organogenesis and oversaw the International business unit.

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Mr. Walthall was the President and Chief Executive Officer of NuTech Medical where he helped build an advanced orthobiologics and wound care business leading to a successful exit via acquisition by Organogenesis. He holds a Bachelor of Science in Engineering Biomedical and Mechanical Engineering (B.S.E.) from Duke University, Durham, NC and a Juris Doctor Samford University – Cumberland School of Law, Birmingham, AL.

- Tim Cunningham, MBA, CPA brings over 30 years of extensive finance and operations leadership experience in the biotechnology and software industries to his work with his public and private Danforth clients, as a CFO with a demonstrated record of success in building startup enterprises into industry leaders and scaling larger entities globally. Mr. Cunningham’s expertise includes financial & strategic planning, P&L management & execution, acquisitions & divestures, raising equity and debt and post-merger integration. Tim is a trusted advisor and subject matter expert in strategic planning and creative, scalable, business design, and has a proven track record of driving growth leading to either a successful exit via sale or IPO. He has raised more than \$500M in private and public equity as well as debt in his career. Mr. Cunningham started his career in public accounting with KPMG in NYC and later with PWC in Boston. Prior to joining Danforth, he served as CFO at Organogenesis where he took the company public in 2018, raising \$144M in equity and \$100M in debt over his tenure. He built the teams, systems, processes, and procedures leading to revenue growth from \$98M in 2016 to a record \$270M in 2020 and the highest rating from each of the sell-side analysts. Mr. Cunningham holds an MBA from Boston University, a BS in Accounting from Boston College and is a CPA in the states of New York & Florida.
- On July 19, 2021, the Corporation announced the amendment of three series of debentures and warrants issued on October 8, 2021, December 30, 2021 and April 21, 2022 to extend their respective maturity dates. The original maturity dates of the 10% unsecured convertible debentures and share purchase warrants of the Company were extended from 24 months after their respective dates of issuance to May 1, 2023. The conversion price of the debentures, the exercise price and other terms of the Warrants remain unchanged.
- On September 21, 2021, the Corporation extended its ongoing collaborative research agreement with Ecole Polytechnique until May 2022. Financial commitments under the extension total \$590 including \$446 due over the next twelve month. The Corporation previously entered into an initial research service agreements with École Polytechnique on June 19, 2015, which stipulated that when the Corporation’s products are commercialized, it must make non-refundable payments to Polyvalor, a shareholder of the Corporation, equal to 1.5% of net sales. In 2018, the term of the initial research service agreement was extended a first time up to May 15, 2021.

**SELECTED FINANCIAL DATA**

The following table sets forth financial information relating to the periods indicated and should be read in conjunction with the July 31, 2021 unaudited financial statements.

**Statements of Loss**

	Q2-22	Q2-21	Change		YTD-22	YTD-21	Change	
	\$	\$	\$ <sup>1</sup>	% <sup>2</sup>	\$	\$	\$ <sup>1</sup>	% <sup>2</sup>
<b>Expenses</b>								
R&D	141	195	(54)	-28%	543	560	(17)	-3%
G&A	367	186	181	97%	805	693	112	16%
Share-based compensation	64	49	15	31%	127	69	58	84%
Financial	332	201	131	65%	671	369	302	82%
<b>Net (Loss) and Comprehensive loss</b>	<b>(904)</b>	<b>(631)</b>	<b>(273)</b>	<b>43%</b>	<b>(2,146)</b>	<b>(1,691)</b>	<b>(455)</b>	<b>27%</b>
<b>(Loss) per share</b>								
Weighted average number of shares outstanding	34,855,186	24,778,743	10,076,443	41%	34,864,928	24,765,656	10,099,272	41%
Basic and diluted loss per share	(0.03)	(0.03)	0.00	2%	(0.06)	(0.07)	0.01	-10%

1. A positive variance represents a negative impact to net loss and a negative variance represents a positive impact to net loss

2. Percentage change is presented in relative values

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**EBITDA(L) Reconciliation** (See “Management’s Responsibility for Financial Reporting” – “Non-IFRS Financial Measures”)

The following table provides a reconciliation of net loss to EBITDA(Loss) for Q2-22 as compared to Q2-21.

	Q2-22	Q2-21	Change		YTD-22	YTD-21	Change	
	\$	\$	\$ <sup>1</sup>	% <sup>2</sup>	\$	\$	\$ <sup>1</sup>	% <sup>2</sup>
<b>Net loss</b>	<b>(904)</b>	(631)	(273)	43%	<b>(2,146)</b>	(1,691)	(455)	27%
Add (deduct)								
Financial Expense	332	201	131	65%	671	369	302	82%
Depreciation	10	4	6	150%	17	21	(4)	-19%
Amortization	8	8	-	0%	16	16	-	0%
<b>EBITDA (L)</b>	<b>(554)</b>	(418)	(136)	33%	<b>(1,442)</b>	(1,285)	(157)	12%

1. A positive variance represents a negative impact to net loss and a negative variance represents a positive impact to net loss

2. Percentage change is presented in relative values

The following commentaries provides a discussion and analysis of our results.

	Q2-22 vs Q2-21	YTD-22 vs YTD-21
<b>Revenues</b>	<ul style="list-style-type: none"> <li>• ORT is a clinical stage company. There were no revenues generated during each of Q2-22 and Q2-21.</li> </ul>	
<b>R&amp;D Expenses</b>	<ul style="list-style-type: none"> <li>• R&amp;D expenses include internal and external expenses. Internal expenses represent mostly salaries and consulting fees for our staff. External expenses include development costs related to our Collaborative R&amp;D contract with Polytechnique as well as specific manufacturing, regulatory, pre-clinical and clinical work to advance our pipeline.</li> <li>• R&amp;D expenses are presented net of R&amp;D tax credits (ITCs) recoverable from the provincial government for Scientific Research and Experimental Development (SR&amp;ED) programs, and also presented net of Government grants which are recognized in reduction of R&amp;D costs and amortized over the term of the project for which the grant was secured.</li> </ul>	
	<ul style="list-style-type: none"> <li>• Net R&amp;D expenses have decreased by 28% between Q2-21 and Q2-22 at \$0.1 million compared to \$0.2 million. The R&amp;D spending has been nominal over Q2-22 due to delays in securing the US-IND for our Rotator Cuff repair program.</li> </ul>	<ul style="list-style-type: none"> <li>• Net R&amp;D expenses for the YTD periods have decreased by 3% between YTD-21 and YTD-22 at \$0.5 million compared to \$0.6 million.</li> </ul>
<b>G&amp;A expenses</b>	<ul style="list-style-type: none"> <li>• G&amp;A expenses include salaries and consulting fees paid to non-R&amp;D staff, professional fees, conferences, travel expenses, as well as investors relation activities.</li> </ul>	
	<ul style="list-style-type: none"> <li>• G&amp;A spending in Q2-22 was \$0.4 million compared to \$0.2 million for the Q2-21 period. The increase in G&amp;A expense is due to an increase in IR spending for the quarter as well as the annual audit fees booked during the quarter.</li> </ul>	<ul style="list-style-type: none"> <li>• G&amp;A spending for YTD-22 was \$0.8 million compared to \$0.7 million for the YTD-21 period. The increase in G&amp;A expense is due to an increase in IR spending compared to last year.</li> </ul>
<b>Share-based compensation (SBC)</b>	<ul style="list-style-type: none"> <li>• Represents the expense related to issuing stock options to staff, consultants and board members. Variances for the comparative quarters include non-recurrent grant to a new Board member as well contractual vesting for members of management on options already outstanding.</li> </ul>	
<b>Financial expenses</b>	<ul style="list-style-type: none"> <li>• Over the last year, the Corporation financed its operations via the issuance of interest-bearing instruments such as CDUs, NCDUs and ITC loans as opposed to equity. While such financial instruments do not lead to an immediate dilution in the total number of shares outstanding in the short term, they lead to increased interest charges.</li> <li>• Between October 2020 and April 2021, the Corporation has completed three (3) CDU financings totalling \$3.2 million. The 3 CDUs are still outstanding and will mature on May 1, 2023 unless converted prior to maturity. Finally, the Corporation secured a \$3.0 million non-convertible debenture in November 2020. All these transactions have impacted the financial expenses.</li> </ul>	
	<ul style="list-style-type: none"> <li>• Financial expenses have increased in Q2-22 compared to Q2-21 at \$0.3 compared to \$0.2 representing a 65% increase. The increase is due to the \$3.0 million NCDU financing secured in Q4-21.</li> </ul>	<ul style="list-style-type: none"> <li>• YTD financial expenses totaled \$0.7 million for the YTD-22 period compared to \$0.4 million for YTD-21.</li> <li>• The increase is due to the new \$3.0 million NCDU financing secured in Q4-21 partly offset by ITC loans reimbursed from the proceeds of the same financing.</li> </ul>
<b>Net Loss for the period.</b>	<ul style="list-style-type: none"> <li>• Net loss increased by 43% between Q2-21 and Q2-22 at \$0.9 million compared to \$0.6 million. The</li> </ul>	<ul style="list-style-type: none"> <li>• Net loss for the YTD-22 period was \$2.1 million compared to \$1.7 million representing a 27% increase. Same as for the QoQ commentaries, the</li> </ul>

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	increase in net loss is due primarily to the increase in financial and G&A expenses.	increase was mainly due to the respective increases in financial costs and G&A expenses.
<b>EBITDA (L)</b>	<ul style="list-style-type: none"> <li>Management believes that our EBITDA (L) performance is more indicative of our operating results as it eliminates the financial costs associated with our financial structure such as CDUs and NCDA financings, and ITC financings (up until Q4-21) as well as depreciation and the amortization of intangible assets.</li> <li>After eliminating the impact of the financial expenses, as well as depreciation, and amortization our EBITDA loss during Q2-22 was \$0.6 million up 33% compared to \$0.4 million for Q2-21.</li> </ul>	<ul style="list-style-type: none"> <li>EBITDA loss for the YTD-22 period was \$1.4 million compared to \$1.3 million for the YTD-21 representing a 12% increase.</li> </ul>

**Selected Balance Sheet Highlights**

The following table sets forth the financial information related to the Corporation’s statements of financial position for the periods indicated and should be read in conjunction with the unaudited financial statements for quarter ended July 31, 2021.

As at,	31-Jul-21	31-Jan-21	Change	Change
	\$	\$	\$ <sup>1</sup>	% <sup>2</sup>
Cash	855	2,379	(1,524)	-64%
Prepays and deposits	99	258	(159)	-62%
Intangible Assets	348	364	(16)	-4%
Total assets	1,610	3,277	(1,667)	-51%
Trade accounts payable and accrued liabilities	78	291	(213)	-73%
Convertible Debentures - Short term	-	1,848	(1,848)	-100%
Convertible Debentures - Long term	2,262	628	1,634	260%
Non-Convertible Debentures	2,216	2,099	117	6%
Embedded derivative	1,194	-	1,194	100%
Total liabilities	6,066	5,078	988	19%
Common shares	7,875	7,706	169	2%
Warrants	1,989	2,080	(91)	-4%
Equity Components of convertible debentures	-	469	(469)	-100%
Contributed surplus	1,832	1,605	227	14%
Deficit	(16,152)	(13,661)	(2,491)	18%

1. A positive variance represents a positive impact to our balance sheet and a negative variance represents a negative impact to our balance sheet.
2. Percentage change is presented in relative values

Selected items	Q2-22 vs YE-21 (Jan 31, 2021)
<b>Cash</b>	<ul style="list-style-type: none"> <li>Cash at the end of Q2-22 was \$0.9 million compared to \$2.4 million at the end of FY-21. There were no financings during the current FY-22, so our liquidities have been used to fund operations and have reduced by \$1.5 million.</li> </ul>
<b>Prepays and deposits</b>	<ul style="list-style-type: none"> <li>Prepays and deposits have decreased by 62% between YE-21 and the end of Q2-22 at \$0.1 million compared to \$0.3 million. Prepays included a prepayment for manufacturing activities which have been completed earlier this year.</li> </ul>
<b>Intangible Asset</b>	<ul style="list-style-type: none"> <li>Intangible assets reflect the net book value of our patents and biopolymer technology acquired from Polyvalor. The nominal reduction between YE-21 and Q2-22 results from amortization charges which were not offset by new investments.</li> </ul>
<b>Total assets</b>	<ul style="list-style-type: none"> <li>The decrease in cash and prepays led to a 51% decrease in our total assets since the end of FY-21.</li> </ul>
<b>Trade payables and accrued liabilities</b>	<ul style="list-style-type: none"> <li>Trade accounts payables and accrued liabilities have decreased by 73% since the start of the FY-22 and reflecting the decrease in external spending and reduction of payable days outstanding.</li> </ul>
<b>Convertible debentures units (CDU)</b>	<ul style="list-style-type: none"> <li>Between October 2019 and April 2020, the Corporation issued \$3.2 million worth of CDUs to fund its operations.</li> <li>At the end of FY-21, the short- and long-term portion of CDUs amounted to \$2.5 million, compared to \$2.3 million at the end of Q2-22.</li> <li>On July 19, 2021, the Corporation announced the amendment of three series of CDUs to extend their respective maturity dates. The original maturity dates of the 10% CDUs and share purchase warrants were extended from 24 months after their respective dates of issuance to May 1, 2023. In addition to the extension, the terms of the CDUs were amended to introduce an anti-dilution clause should the Corporation issue shares below the initial conversion price of the debentures prior to their maturity. Finally, the maturity date of the new CDUs may be</li> </ul>



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	<p>accelerated should the Corporation raise a minimum of \$10 million cumulative financing before their conversion/maturity.</p> <ul style="list-style-type: none"> <li>As a result of amending the terms of the CDU described above, the Corporation determined that the conversion option of the CDUs had to be considered as an embedded derivative and be classified as a liability instrument. Therefore, the Corporation derecognized the \$0.5 million carrying amount of the conversion option initially classified as an equity component and recorded the fair value of \$1.2 million as a liability. (See “Embedded Derivative” below)</li> <li>Also, as a result of this amendment, and considering all CDUs are now presented as long-term liabilities, our working capital improved by \$1.8 million.</li> </ul>
<b>Non-convertible Debentures (NCDU)</b>	<ul style="list-style-type: none"> <li>During Q4-21 the Corporation secured a \$3.0 million NCDU financing that enabled the repayment of ITC loans and increased the Corporation’s liquidities. The increase of \$0.1 million between YE-21 and Q2-22 represents accretion expense for the YTD-22 period.</li> </ul>
<b>Embedded Derivative</b>	<ul style="list-style-type: none"> <li>The Embedded derivative was created following the amendment of the CDU described above. By extending the terms and by introducing a conversion option, a \$1.2 million embedded derivative was created.</li> <li>Going forward, any change in the Fair Value of the Conversion Option of the CDUs (“FVCO”) will be recorded as a financial expense in the statements of loss, as a gain or loss on embedded derivative related to convertible debentures.</li> <li>Changes to the FVCO will take place based on the following 3 scenarios: 1) reduction of the FVCO following quarterly re-evaluation of the FVCO; 2) exercise of the conversion option by the holder; and 3) repayment or maturity.</li> </ul>
<b>Total Liabilities</b>	<ul style="list-style-type: none"> <li>Total liabilities have increased slightly between YE-21 and Q2-22. The \$1.0 million increase results from the creation of the embedded derivative discussed above, which has been partly offset by the decrease in trade payables.</li> </ul>
<b>Common Shares</b>	<ul style="list-style-type: none"> <li>Common shares have increase by \$0.2 million during YTD-22 due to the conversions of some CDUs for \$0.1 million as well as \$0.1 million from the exercise of warrants.</li> </ul>
<b>Warrants</b>	<ul style="list-style-type: none"> <li>Warrants decreased by \$0.1 million following the exercised of some warrants during YTD-22.</li> </ul>
<b>Equity component of CDUs</b>	<ul style="list-style-type: none"> <li>The equity component of the convertible debentures represented the fair value of the conversion features of these CDUs. The equity component was eliminated following the amendment of the CDUs and replaced by the embedded derivative classified as long-term liability. (See CDUs above)</li> </ul>
<b>Contributed Surplus</b>	<ul style="list-style-type: none"> <li>The \$0.2 million increase relates to net impact for stock options issued during the quarter.</li> </ul>
<b>Deficit</b>	<ul style="list-style-type: none"> <li>Increase reflects the performance of the Corporation for the YTD-22 period. (See “Statement of Loss” commentaries)</li> </ul>

**SELECTED QUARTERLY FINANCIAL INFORMATION**

The following table sets out the Corporation’s selected unaudited quarterly financial information for the eight quarters ended July 31, 2021. This information is derived from unaudited quarterly financial statements prepared by management in accordance with IFRS. The following quarterly information is presented on the same basis as the audited financial statements and should be read in conjunction with those statements and their accompanying notes.

	Q2-22	Q1-22	Q4-21	Q3-21	Q2-21	Q1-21	Q4-20	Q3-20
R&D Expenses (Net)	141	402	390	191	195	365	142	421
G&A expenses	367	438	472	342	186	507	136	254
Share-based compensation	64	63	112	101	49	20	74	36
Financial expenses (income)	332	338	294	179	201	168	125	49
Net (loss) for the quarter	(904)	(1,241)	(1,268)	(813)	(631)	(1,060)	(477)	760
Loss per share (Basic and diluted):	0.03	0.04	0.03	0.07	0.04	0.02	0.03	0.03
<b>EBITDA (Loss)</b>	<b>(554)</b>	<b>(888)</b>	(951)	(611)	(413)	<b>(862)</b>	(323)	(682)

(See “Management’s Responsibility for Financial Reporting” – “Non-IFRS Financial Measures”)

Notes	Valuable information
<b>R&amp;D expenses (Net of ITCs and Grants)</b>	<ul style="list-style-type: none"> <li>Net R&amp;D expenses represent gross R&amp;D expenses less ITC provisions related to these costs as well as the amortization of grants specific to ongoing R&amp;D programs.</li> <li>Net R&amp;D expenses decreased 27% compared to the prior Q1-21 quarter.</li> </ul>

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	<ul style="list-style-type: none"> <li>R&amp;D activities picked up late last year as the Corporation completed its CMC batch manufacturing and other IND related activities.</li> <li>Once the IND for our Ortho-R Rotator Cuff Repair program is secured, we expect R&amp;D expenses to increase to support the projected Phase I/II clinical trial for Rotator cuff repair.</li> </ul>
<b>G&amp;A expenses</b>	<ul style="list-style-type: none"> <li>G&amp;A expenses consist primarily of salaries or consulting fees for non-scientific management and staff, professional fees for audit and tax related matters, in-house counsel, insurance, and fees paid to IR firms.</li> <li>G&amp;A expenses have fluctuated from quarter to quarter.</li> <li>G&amp;A expenses have increased since Q3-21 due to incremental IR spending.</li> <li>The Q1-21 amount includes a non-recurring \$0.3 million salary adjustment paid to senior management for having agreed to receive non-cash remuneration between July 2019 and April 2020.</li> <li>Other expenses, such as rent, insurance, and office expenses, have been relatively stable and had no significant impact on the overall spending.</li> </ul>
<b>Share-Based Compensation</b>	<ul style="list-style-type: none"> <li>Share-based compensation are costs for the issuance of stock options to senior management, staff, board of directors, scientific advisory board and consultants working for the Corporation.</li> <li>Share-based compensation fluctuates as a results of staff changes, and due to the timing of expense recognition associated with the vesting of the options issued.</li> </ul>
<b>Financial expenses</b>	<ul style="list-style-type: none"> <li>Financial expenses are costs associated with the CDUs, NCDUs, ITC loans, term loan and notes payable.</li> <li>The increase in financial expenses over the recent quarters results from the CDUs and NCDUs financings closed over the last 2 years.</li> <li>Interest charges on the CDUs may go down over time as CDU holders opt to convert their debenture prior to maturity.</li> <li>Q2-22 was the third quarter showing the full impact of the NCDU financing closed on November 30, 2020.</li> <li>ITC loans have been repaid in Q4-21 and will no longer impact our financial expenses going forward.</li> </ul>
<b>Net loss</b>	<ul style="list-style-type: none"> <li>ORT’s net loss is mainly driven by the level of R&amp;D spending made to advance its R&amp;D programs (Ortho-R, Ortho-M, and Ortho-C) as well as the financial expenses related to its capital structure.</li> </ul>
<b>EBITDA (Loss)</b>	<ul style="list-style-type: none"> <li>EBITDA (Loss) (See “Management’s Responsibility for Financial Reporting” – “Non-IFRS Financial Measures”) eliminates the impact of the CDU, NCDU, ITC and other financings which reflect the Corporation’s financing strategy adopted to attract the required capital to fund its operations.</li> <li>After eliminating such expenses, the EBITDA (Loss) has fluctuated with the level of G&amp;A and R&amp;D expenses. The EBITDA loss has reduced by 38% over the prior Q1-22 quarter due to the reduction in R&amp;D spending due to delays in the start of our Phase I/II Ortho-R Rotator Cuff trial.</li> </ul>

LIQUIDITIES AND CAPITAL RESSOURCES

For the 6-month period ended on,	2021-07-31	2020-07-30	Change	
			\$ <sup>1</sup>	% <sup>2</sup>
<b>Operating activities:</b>				
Net loss from operations	(2,146)	(1,691)	(455)	27%
Other items not affecting cash	581	818	(237)	-29%
Changes in non-cash working capital	(25)	402	(427)	-106%
Cash used in operations	(1,590)	(471)	(1,119)	238%
<b>Investing activities:</b>				
Cash used in investing activities	(33)	-	(33)	100%
<b>Financing activities:</b>				
Cash provided by financing activities	135	192	(57)	-30%
Effect of foreign exchange on cash	(36)	-	(36)	100%
<b>(Decrease) increase in cash</b>	<b>(1,524)</b>	<b>(279)</b>	<b>(1,245)</b>	<b>446%</b>
<b>Cash, beginning of period</b>	<b>2,379</b>	<b>302</b>	<b>2,077</b>	<b>688%</b>
<b>Cash, end of period</b>	<b>855</b>	<b>23</b>	<b>832</b>	<b>3617%</b>

1. A positive variance represents a positive impact to cash flows and a negative variance represents a negative impact to cash flows  
 2. Percentage change is presented in relative values

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	<b>Q2-22 vs Q2-21</b>
<b>Cash used in operations</b>	<ul style="list-style-type: none"> <li>• Cash used in operations represents the cash flows from operations, excluding income and expenses not affecting cash plus changes in non-cash working capital items.</li> <li>• Cash used in operations has increased by 238% at \$1.6 million for the YTD-22 period as compared to \$0.5 million for YTD-21 period. The \$1.1 million increase results from a \$0.5 million increase in net loss, and a \$0.2 million decrease in items not affecting cash. Items not affecting cash decreased when compared to prior year mainly due to conversion of \$0.4 million of consulting fees into CDU in YTD-21 compared to nil for the YTD-22. Changes to working capital items also contributed to use \$25 in YTD-22 compared to providing \$0.4 million for YTD-21 representing a negative cash impact of \$0.4 million between the 2 periods.</li> </ul>
<b>Cash used in investing activities</b>	<ul style="list-style-type: none"> <li>• The Corporation used \$33 to acquire equipment during YTD-22 compared to nil for YTD-21. The equipment will be used by the clinical trial centers to perform work required as per our Clinical trial protocol for the upcoming Ortho-R Phase I/II trial.</li> </ul>
<b>Cash provided by financing activities</b>	<ul style="list-style-type: none"> <li>• Financing activities contributed \$0.1 million during YTD-22 period including government grant to support R&amp;D work, as well as \$0.1 million from the exercise of warrants. This compares to \$0.2 million for YTD-21 representing mainly \$0.4 million for the issuance of CDUs, less \$0.2 million for the repayment of ITC loans.</li> </ul>
<b>Cash, End of the period</b>	<ul style="list-style-type: none"> <li>• The Corporation ended Q2-22 with \$0.9 million of cash compared to almost nil at the end of Q2-21 representing a \$0.8 million increase. The series of financings completed during the past year helped increase the cash position which was used to fund operations.</li> </ul>

**Cash, and Working Capital**

As at,	31-Jul-21	Jan 31, 2021	Change	
			\$ <sup>1</sup>	% <sup>2</sup>
Cash	<b>855</b>	2,379	(1,524)	-64%
Total current assets	<b>1,173</b>	2,840	(1,667)	-59%
Accounts payables and accrued liabilities	<b>303</b>	291	12	4%
Convertible debentures - Short term portion	-	1,848	(1,848)	-100%
Total current liabilities	<b>342</b>	2,311	(1,969)	-85%
Working Capital	<b>831</b>	529	302	57%

1. A positive variance represents a positive impact and a negative variance represents a negative impact

2. Percentage change is presented in relative values

Cash at the end of Q2-22 was \$0.9 million as compared to \$2.4 million at the end of YE-21. Despite the cash used to fund operations and no financing secured since the start of fiscal year 2022, our working capital has improved by \$0.3 million between YE-21 and Q2-22 following the extension of CDUs which contributed to improve our working capital by \$1.8 million. All CDUs are now maturing on May 1, 2023.

ORT continued to make significant progress towards the start of its first human trial on Ortho-R for rotator cuff repair. Despite some operational delays due to our interaction with the FDA, the Corporation expects to meet this important corporate milestone in FY-22. During prior periods, the Corporation has demonstrated its ability to raise the necessary capital to support its operations and achieve development milestones. However, there is no assurance that the Corporation will be able to secure the necessary financing to fund its various development programs. Management has continued to implement IR and financing initiatives to attract the required capital to fund its operations and deliver R&D and corporate milestones as demonstrated by the NCDU financing closed in Q4-21. ORT has enough financial resources to start its Ortho-R rotator cuff tear repair clinical program before the end of FY-22 (See “Overview of the Business” and “Going concern”).

**Future financing**

As at July 31, 2021, ORT had 18.3 million warrants outstanding with an average exercise price of \$0.52. 14.7 million warrants are subject to an acceleration clause. If the average VWAP of the Corporation’s shares over any twenty (20) consecutive trading days is greater or equal to \$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. The extent to which these warrants are exercised will be a function of the market price of the Corporation’s underlying common shares and investors’ view of the opportunity for shareholder value creation over the investment time for each individual investor. If the acceleration clause had been exercised for all warrants outstanding at the end of Q2-22 and for which the acceleration clause applied, the maximum influx of cash to the Corporation would have been approximately \$7.3 million. Assuming all warrants are exercised prior to their maturity a total of \$9.5 million could be raised.

The Corporation’s use of available funds over the coming year is of utmost concern to the Board. Since the extent and timing of warrant exercise as a source of financing are uncertain, management continues to look for alternative sources of financing to secure the required

## Ortho Regenerative Technologies Inc.



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capital necessary to fund its operations and development projects. Management's focus is on securing equity-based financings from Canadian and US based institutional and/or accredited investors. The Corporation is also actively promoting its technologies to strategic partners.

#### Discussion of operating cash requirements

All programs in the Corporation's current portfolio will require a significant investment to increase their market value (through, for example, clinical trials) or to attract a strategic partner. We estimate that \$30 million will be required to bring our rotator cuff (Ortho-R), meniscus (Ortho-M), and cartilage (Ortho-C) programs to market. There are several areas where duplication between programs can provide savings such as the manufacture of the chitosan material, which is common across our product platform. We therefore do not need to replicate several manufacturing activities, or some associated costs, for each of the projects.

Ortho-R for the repair of rotator cuff tears is a clinical development stage program and represents our lead product for commercialization. We currently estimate that an additional investment of at least \$5 million will be required to provide proof of concept in human and another \$10 million to bring the same program to commercialization.

Ortho-M (meniscus) is the Corporation's second candidate and is also in a development phase. Proof of efficacy in a large animal preclinical model is expected to take place in the coming fiscal year. Ortho-M's development pathway and plan will be similar to Ortho-R and will benefit from all cGMP activities performed on scaling-up Ortho-R. Consequently, management estimates that \$1.5 million will be required prior to submitting an IND application prior to testing Ortho-M in human for meniscus tear repair.

Ortho-C and Ortho-V are currently at earlier stage of development and management does not intend to commit any sums to the advancement of these projects until its successfully advances Ortho-R and Ortho-M in human clinical testing.

In order to successfully advance its current R&D programs, ORT entered on into a Collaborative R&D Agreement with Polytechnique on June 19, 2015 to ensure access to Polytechnique's staff, expertise and laboratories. The agreement was amended in 2018 to extend the term up to May 15, 2021, and further extended on September 21, 2021 until May 15, 2022.

#### Statement of Compliance

The unaudited interim financial statements included in this MD&A for the quarter ending July 31, 2021 have been prepared in accordance with *International Financial Reporting Standards* as issued by the *International Accounting Standards Board ("IASB")* as well as with those standards and interpretations as issued by the *International Financial Reporting Interpretations Committee ("IFRIC")* issued and effective or issued and early adopted as at the time of preparing these interim financial statements.

#### Use of Estimates and Judgements

Reference should be made to the Corporation's 2021 annual financial statements, *note 3*, for an extended description of the information concerning the Corporation's significant judgments, estimates and assumptions that have the most significant effect on the recognition and measurement of assets, liabilities, income and expenses.