



(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 "Ortho RTI") provides an overview of the Corporation's operations, performance and financial results our first quarter ended on April 30, 2021 and compares those of the same period in fiscal year 2020. 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 Ortho RTI's Board of Directors on June 29, 2021. This document should be read in conjunction with the unaudited financial statements and notes thereto for the fiscal quarter ended on April 30, 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 Ortho RTI, including the Annual Information Form, is available online on SEDAR at <a href="www.sedar.com">www.sedar.com</a>.

#### 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 April 30, 2021, the Corporation incurred a net loss of \$1,241, and used cash in operations of \$820. As at April 30, 2021, the Corporation had a working capital balance deficiency of \$1,093. Considering the above, the Company's performance raises significant doubt about the Company's 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 ended April 30, 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 &	Calendar & Financial		perations erations
CDU	Convertible Debenture Units	API	Active Pharmaceutical Ingredient
EBITDA (L)	EBITDA Loss	CDUs	Convertible debenture units
FY-20	Fiscal Year ended January 31, 2020	CMC	Chemistry Manufacturing and Controls
FY-21	Fiscal Year ended April 30, 2021	cGMP	current Good Manufacturing Practice
FY-22	Current Fiscal Year ending January 31, 2022	СМО	Contract Manufacturing Organization
G&A	General and Administrative	CSE	Canadian Securities Exchange
IR	Investors Relations	FDA	US Food and Drug Administration
ITC	Investment tax credits	IND	Investigational New Drug application with the FDA
Q1-22	First quarter FY-22	MCRA	MCRA, LLC, a US based orthopedic specialty CRO
Q4-21	Fourth quarter FY-21	MRI	Magnetic Resonance Imaging
Q3-21	Third quarter FY-21	MTA	Material Transfer Agreement
Q2-21	Second quarter FY-21	NCDUs	Non-Convertible Debenture Units
Q1-21	First Quarter FY-21	Ortho RTI	Ortho Regenerative Technologies Inc.
Q4-20	Fourth quarter FY-20	Ortho-C	Proprietary biopolymer for Articular Cartilage repair
Q3-20	Third quarter FY-20	Ortho-M	Proprietary biopolymer for Proprietary Biopolymer for
Q2-20	Third quarter FY-20		Meniscus repair
SR&ED	Scientific Research and Experimental	Ortho-R	Proprietary biopolymer for Rotator cuff repair
	Development	Ortho-V	Proprietary biopolymer for Osteoarthritis healing
R&D	Research and Development	OTCQB	US over-the-counter venture trading market
YTD	Year to date	Polytechnique	Ecole Polytechnique de Montreal
YE-21	Year-end 2021 – April 30, 2021	PRP	Platelet-rich plasma
YE-20	Year-end 2020 – January 31, 2020	Pre-RFD	Pre-Request for Designation
W/C	Working Capital, defined as short-term assets less short-term liabilities		

## **OVERVIEW OF THE BUSINESS AND BUSINESS STRATEGY**

Ortho RTI 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, and senior researchers at Polytechnique are still actively involved in the day-to-day development of Ortho RTI's pipeline.

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

- o <u>Patent Family No.1</u>: 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.
- <u>Patent Family No.2</u>: Novel formulation of physiological biopolymer-inorganic salt solution/blood mixtures for tissue repair. <u>This patent family was abandoned on November 9, 2019</u>. 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.
- o <u>Patent Family No.3</u>: 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**

Ortho RTI's lead program is Ortho-R, a biopolymer-PRP bioactive 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).

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

Program	Development Stage	Indication	Details
Ortho-R	Clinical Phase I/II	Rotator Cuff	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. The Corporation received a clinical hold letter from the FDA on June 4, 3021 and is aiming to respond before the end of Q2-22. After clearance of our IND by the FDA and site's Clinical Review Board's approval, enrollment may start in 8-10 clinical sites which are undergoing qualification, budget negotiation and training procedures. Enrollment is expected to start by the end of Q3-FY22 and to be completed 6 to 8 months after.
Ortho-M	Pre-Clinical	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. The next stage is to validate our model in a large animal pivotal study starting in FY-22, before entering into human clinical trial.
Ortho-C	Pre-Clinical	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.
Ortho-V	Feasibility	Osteoarthritis	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.

Considering the significant bioactivity and residency of our proprietary biopolymer – PRP implants, Ortho RTI 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 Drug-biologics formulation that contains a biopolymer, a lyoprotectant and a clot activator. This freeze-dried formulation can be 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 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 Q1-22, 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

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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. <a href="https://www.orthorti.com/cms">https://www.orthorti.com/cms</a> files/phpfQwJvt.pdf

#### Manufacturing & CMC:

Our cGMP clinical lot production has been successfully completed during Q1-22 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 in the 2021 calendar.

#### 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 various physicochemical interacting actions on various cell types and other PRP components, therefore supporting a combination product with the Ortho-R reconstituted in PRP considered a Drug/Biologics that 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.

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. The FDA has requested additional Chemistry, Manufacturing, and Control ("CMC") related information. The clinical hold received by the Corporation is a process by which the FDA can delay the start of a clinical trial in order to request information not previously included in the sponsor's IND application. The Company is confident in its ability to address and provide the FDA with the required information and testing data over the coming weeks (the "Supplemental IND information"). The FDA is then expected to respond to our Supplemental IND information within 30 days after filing our response.

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. Activities focus were mainly on protocol, patients' assessment EDC system, MRI procedure protocol and system, clinical sites considerations and qualifications. Assuming clearance of our IND application by the FDA in fiscal Q3-22, patients' enrollment would be expected to start by then end of Q3-22, 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 in fighting the pandemic will favor a substantial increase in elective rotator cuff repair surgeries across the United States in 2021 and 2022 compared to 2020. This will play a big role in our ability to accelerate patient screening and recruitment for inclusion in our upcoming Phase I/II clinical trial.





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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:

					Caler	ıdar (	Calendar Quarters/Years					
Past and Projec	ted Milestones	Calendar Year 2019-2023	2019	2020	Q1-21	Q2-21	Q3-21	Q4-21	H1-22	Н2-22	H1-23	
Corporate /												
Strategic	MTA collaboration - initial Phase	Initial Phase	$\square$									
	MTA collaboration - Step 2	On-Hold (Covid-19)		0								
	Licensing Agreement - Ingenew Phar	ma		Ø								
Finance	US OTC-QB Listing											
	Debenture Financings		Ø	Ø								
	Private Placement - Unit Offering (\$	2.6M)		Ø								
	Non-Convertible Debenture Financia	ng (\$3M)		Ø								
Ortho-R	CMC Manufacturing	Scale-up	<b>→</b>	☑								
Rotator Cuff		Stability 2yrs - shelf life data	<b>→</b>	Ø								
Repair Progam		Stability 3yrs - shelf life data	<b>→</b>									
		Clinical batch		<b>→</b>	Ø							
	6-month pivotal animal trial	in-life portion	$\square$									
		results		Ø								
	Pre-IND Meeting - FDA		Ø									
	US-FDA IND	Filing Pre-RFD		Ø								
		Drug/Biologic Designation		Ø								•
		IND Preperation		Ø								
		IND filing				Ø						
		IND approval				0						Clinical Hold June 3 <sup>rd</sup> , 21
	US Phase I/II Clinical trial	CRO Selection	$\square$									
		Protocol completion		Ø								
		Lead Investigator selection		Ø	***************************************							
		Study sites selection			<b>→</b>							
		Clinical sites qualification & training			******************							
		Phase I/II trial START					<b>→</b>					
		First patient enrolled										no change from prior MD&A
		50% enrolment completed										
		enrolment completed			******************							no change from prior MD&
		12-mth patient follow up completed										no change from prior MD&A
		Study results			***************************************							no change from prior MD&A
Ortho-M	6-month Large animal pivotal trial	CRO Selection and Protocol			Ø							
Meniscus		in-life portion Start					<b>→</b>					
Program		3-mth in life data	-									•
2		in-life portion Ends										
		study-results										•
		Initiation	Ø	Com	pleted	d						-
		■ Current Target Completion	0	On-l	lold							

## First Quarter 2022 CORPORATE HIGHLIGHTS

#### Ortho-R Program

• On April 6, 2021, the Corporation announced that it had 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.

## **Financing and Other Corporate Highlights**

- On February 4, 2021 Ortho RTi announced that it has retained Westwicke, an ICR company, as its investor relations advisors for the U.S. markets. Westwicke Partners / ICR Westwicke Partners provides customized strategic investor relations programs and independent capital markets advice to public and private healthcare companies. Westwicke focuses on the healthcare sector exclusively and is headquartered in Baltimore with regional offices in Boston, New York, San Diego, San Francisco and London.
- On February 24, 2021 Ortho RTI announced the appointment of Patrick O'Donnell to its Board of Directors. Patrick O'Donnell is the
  President and Chief Executive Officer of HD LifeSciences, a prominent life sciences executive with over 25 years of experience guiding
  companies in both the pre-commercial and commercial stages. Mr. O'Donnell brings a comprehensive understanding of the medical
  device, orthobiologics and biomaterial industries in the orthopedic, spine, neurosurgery, and sports medicine markets. Prior to his role

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at HD LifeSciences, he was Executive Vice-President & General Manager of Commercial Operations for Bonesupport A.B.;Co-Founder and CEO for Proteothera, Inc.; President and CEO for Histogenics Corporation / Prochon Biotech, Inc., Director of Global Marketing for Confluent Surgical, Inc., and sales and marketing positions of escalating responsibility for Johnson & Johnson / DePuy Spine. Patrick graduated from the University of Wisconsin-Madison. The Company also announced the retirement of Prof Michael Buschmann and Prof. Caroline Hoemann from its Board of Directors, effective February 22, 2021.

• On March 31, 2021, Ortho RTI announced that its common shares were eligible for electronic clearing and settlement through the Depository Trust Company ("DTC") in the United States.

## **Events Subsequent to the end of the quarter**

- On June 4, 2021, the Corporation announced that it has 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 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. 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.





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# **SELECTED FINANCIAL DATA**

The following table sets forth financial information relating to the periods indicated and should be read in conjunction with the April 30, 2021 unaudited financial statements.

## **Statements of Loss**

	Q1-22	Q1-21	Change	•
	\$	\$	\$ <u>1</u>	% <mark>²</mark>
Expenses				
R&D	463	404	59	15%
Provision for (recovery) of ITCs	(33)	(39)	6	-15%
Government grant recognized in reduction of R&D costs	(6)	-	(6)	100%
R&D Expenses (Net)	424	365	59	16%
ITC Recovery %	<b>7</b> %	10%	-3%	
G&A	416	507	(91)	-18%
Share-based compensation	63	20	43	215%
Financial	338	168	170	101%
Total Expenses	1,241	1,060	181	17%
Net Loss	(1,241)	(1,060)	(181)	17%
Loss per share				
Basic and diluted	0.04	0.04	-	0%
Weighted average number of shares outstanding	34,872,899	24,752,424	10,120,475	41%

<sup>1.</sup> A positive variance represents a negative impact to net loss and a negative variance represents a positive impact to net loss

**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 Q1-22 as compared to Q1-21.

	Q1-22	Q1-21	Change	
	\$	\$	\$ <u>1</u>	% <u>²</u>
Net loss	(1,241)	(1,060)	(181)	17%
Add (deduct)				
Financial Expense	338	168	170	101%
Depreciation	7	22	(15)	-68%
Amortization	8	8	-	0%
EBITDA (L)	(888)	(862)	(26)	3%

<sup>1.</sup> A positive variance represents a negative impact to net loss and a negative variance represents a positive impact to net loss

<sup>2.</sup> Percentage change is presented in relative values

	Q1-22 vs Q1-21
Revenues	• Ortho RTI is a clinical stage company. There were no revenues generated during each of Q1-22 and Q1-21.
R&D expenses (Gross)	• R&D expenses include internal and external expenses. Internal expenses represent mostly salaries and consulting fees for our staff. External expenses include all development costs related to work performed under our Collaborative R&D contract with Polytechnique as well as specific manufacturing activities, regulatory, pre-clinical and clinical work to advance our pipeline. R&D expenses (Gross) are presented prior to considering R&D tax credits (ITCs) recoverable from the provincial government for Scientific Research and Experimental Development (SR&ED) programs, and prior to government grants.
	• Gross R&D expenses for Q1-22 was slightly higher than Q1-21 at \$463 compared to \$404, representing a 15% increase. In addition to R&D expenses related to its long-term service contract with Polytechnique which remained constant between the two reported periods, the Corporation completed its cGMP manufacturing batch for the upcoming Ortho-R clinical trial during Q1-22, as well as other activities leading to the filing of its IND application with the FDA. Last year, other gross R&D expenses related mainly in preclinical activities related to its Ortho-R program.

<sup>2.</sup> Percentage change is presented in relative values





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ITCs	<ul> <li>ITCs represent R&amp;D tax credits recovered from the provincial government for SR&amp;ED programs. Claims can be made for eligible R&amp;D expenses and the recovery rates vary depending on the nature of the expense. Staff compensation typically lead to a greater recovery than external costs. Since going public in 2017, the Corporation lost its CPCC ("Canadian controlled private company") status, and consequently in only eligible to refundable Quebec credits, while federal credits are applied against future profits.</li> <li>The Corporation will favour Quebec based suppliers where possible in order to claim SR&amp;ED refundable credits and reduce the net costs of performing its R&amp;D programs.</li> <li>Ortho-R has opted to select MCRA, a US-based CRO, to help with the planning and execution of its Ortho-R clinical trial with most centers to be located in the US. The Corporation believes this is the best strategy to optimize the results of the study and create the most value for its shareholders. This decision will likely reduce the SR&amp;ED claims going forward on the Ortho-R program. However manufacturing and pre-clinical activities if required for the meniscus (Ortho-M) and cartilage (Ortho-C) programs will take place in Quebec and help maximize SR&amp;ED claims.</li> <li>ITCs accrued for Q1-22 were \$33 as compared to \$39 for Q1-21. The ITC's recovery rate has decreased slightly between the 2 periods at 7% compared to 10%. The decrease in recovery rate is due to a lower</li> </ul>
Government grant recognized in reduction of R&D	<ul> <li>percentage of eligible expenses for SR&amp;ED reimbursement.</li> <li>During Q1-22, the Corporation secured a \$150 grant for conducting its R&amp;D activities. The grant is to be amortized over the term of the 2-yr agreement. \$75 was received during Q1-22, the balance is expected during FY-23.</li> </ul>
Net R&D Expenses	<ul> <li>\$6 was recognized during the quarter.</li> <li>After taking into account the ITCs and the amortization of the government grant, the Net R&amp;D costs have increased by 16% between Q1-21 and Q1-22 at \$424 compared to \$365.</li> </ul>
G&A expenses	<ul> <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> <li>G&amp;A spending in Q1-22 was lower to Q1-21 at \$416 compared to \$507 representing a 18% decrease despite the increase in professional and IR fees and activities. Year-end audit fees for \$74 were booked during Q1-22 as opposed to being amortized last year. Also, there was a \$267 non-recurrent management fee incurred in Q1-21 compared to nil in Q1-22.</li> </ul>
Share-based compensation (SBC)	• 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.
Financial expenses	<ul> <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 separate CDU financings totalling \$3.2 million. Finally, the Corporation has secured a \$3.0 million non-convertible debenture in November 2020. All these transactions have impacted the financial expenses.</li> <li>Financial expenses have increased significantly in Q1-22 compared to Q1-21 at \$338 compared to \$168 representing a 101% increase. The increase is due to the new \$3 million NCDU financing secured in Q4-21, as well as the 3<sup>rd</sup> CDU financing secured in Q1-21 which was outstanding for the full quarter in Q1-22 compared to only a few weeks in Q1-21.</li> <li>Interest on debentures representing \$144 were incurred in Q1-22 as compared to \$55 in Q1-21, while effective interest on the debentures of \$146 were booked in Q1-22 as compared to \$52 in Q1-21.</li> <li>ITC loans were reimbursed in Q4-21 and no ITC borrowing costs have been recognized during Q1-22 thus providing savings over last year's comparable expense of \$43.</li> </ul>
Net Loss for the period.	• Net loss increase by 17% between Q1-21 and Q2-22 at \$1,241 compared to \$1,060. The \$181 increase in net loss is due primarily to the \$170 increase in financial expenses as well as respective increases in net R&D expenses and share-based compensation of \$59 and \$43 respectively.
EBITDA (L)	<ul> <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 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 Q1-22 was \$888 compared to \$862 for Q1-21, representing a 3% increase.</li> </ul>





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

# **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 April 30, 2021.

		31-Jan[WC1]-	21 Change <u>-{<sup>1,-2</sup>}</u>	
As at,	30-Apr-21	21		
		(restated 3)		
	\$	\$	\$ <u>1</u>	% <mark>²</mark>
Cash	1,613	2,379	-766	-32%
ITC (current & non-current)	176	143	33	23%
Prepaids and deposits	157	258	-101	-39%
Intangible Assets	356	364	-8	-2%
Total assets	2,423	3,277	-854	-26%
Trade accounts payable and accrued liabilities	319	291	28	10%
Accrued interest on debentures	156	172	-16	-9%
Government grant – Short term	57	-	<i>57</i>	100%
Convertible Debentures – short-term	2,530	1,848	682	37%
Government grant - Long term	12	-	12	100%
Convertible Debentures – long-term	-	628	-628	-100%
Non-Convertible Debentures	2,155	2,099	56	3%
Long-term loans	40	40	-	0%
Total liabilities	5,269	5,078	191	4%
Common shares	7,858	7,706	152	2%
Warrants	2,070	2,080	-10	0%
Equity component of CDU	460	469	-9	-2%
Contributed surplus	1,668	1,605	63	4%
Deficit	(14,902)	(13,661)	-1,241	9%

<sup>1.</sup> A positive variance represents a positive impact to our balance sheet and a negative variance represents a negative impact to our balance sheet.

The comparative figures of the statement of financial position were restated to reflect a correction to the current portion of the convertible debentures as at January 31, 2021, by reclassifying an amount of \$1,848 from long-term liabilities to current liabilities.



Selected items	Q1-22 vs YE-21
Cash	• Cash at the end of Q1-22 was \$1,613 compared to \$2,379 at the start of the year. There were no financings during the quarter, so our liquidities were used to fund operations and reduced by \$766.
ITCs	• Despite the reduction of our ITC recovery rates for Q1-22 (See "Statement of Loss" commentaries) our ITCs assets increased by \$33 representing the amount of ITC provision for Q1-22 while no collection of prior provisions were collected.
Prepaids and deposits	• Prepaids and deposits have decreased by 39% between the end of FY-21 and the end of Q1-22 at \$157 compared to \$258. Prepaids included a prepayment to our CMC supplier to secure more favorable timelines for the manufacturing activities completed in Q1-22. Most CMC costs for Q1-22 were funded via a reduction of our prepaid position as opposed to using cash.

<sup>2.</sup> Percentage change is presented in relative values

Comparative figures restated





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

Intangible Asset	• Intangible assets reflect the net book value of our patents and biopolymer technology acquired from Polyvalor. The nominal reduction between YE-21 and Q1-22 results from amortization charges which were not offset by new investments.
Total assets	• The decrease in cash and prepaids led to a 26% decrease in our total assets between the end of FY-21 and Q1-22.
Trade payables and accrued liabilities	• Trade accounts payables and accrued liabilities have increased by 10% during Q1-22 as a result of the timing of payments of our trade payables.
Government Grant	• The \$57 amount in short term and \$12 in long-term represent the portion of the \$75 government grant secured during Q1-22 and to be recognized over such periods.
Convertible debentures units (CDU)	<ul> <li>Between October 2019 and April 2020, the Corporation issued \$3,204 worth of CDUs to fund its operations including a first closing of \$1,644 on October 8, 2019, a second closing of \$500 on December 30, 2019, and a third closing of \$1,060 on April 21, 2020. At the end of FY-21, the CDUs plus accreted interest net of the fair value allocated to the conversion option of the debentures and the fair value allocated to the warrants issued as part of the CDU financings amounted to \$2,476 (short and long term portion) compared to \$2,530 at the end of Q1-22.</li> <li>Considering the respective maturities of CDU financings, the full value of the CDU as at Q1-22 are presented as short-term while \$1,848 relating to the October 2019, and December 2019 CDUs was recorded as short term as at January 31, 2021 and \$628 as long-term representing the value of the April 2020 CDUs.</li> </ul>
Non-convertible Debentures (NCDU)	• During Q4-21 the Corporation secured a \$3,000 NCDU financing that enabled the repayment of ITC loans and increased the Corporation's liquidities. The increase of \$56 between YE-21 and Q1-22 represents accretion expense for the Q1-22 period.
Total Liabilities	• Total liabilities have increased slightly between YE-21 and Q1-22. The \$191 increase comes mainly from a small \$28 increase in trade payables and accruals, \$69 for the total non-amortized portion of the \$75 government grant, total \$155 accretion expense on the CDU and NCDU debentures less \$45 reduction of CDUs following conversions.
Common Shares	• Common shares have increase by \$152 during Q1-22 following \$56 conversions of CDUs as well as \$73 from the exercise of warrants and \$23 of shares issued for settlement of invoices related to IR services.
Warrants	Warrants decreased by \$10 following the exercised of some warrants during Q1-22.
Equity component of Convertible debentures	• The equity component of the convertible debentures represents the fair value of the conversion features of these CDUs. The outstanding debentures can be converted at \$0.30 until their respective 2-yr maturity. The \$9 decrease for Q1-22 relates to the fair value allocated to the CDU converted during the quarter.
Contributed Surplus	The \$63 increase relates to net impact for stock options issued and exercised during the quarter.
Deficit	• Increase reflects the performance of the Corporation during Q1-22. (See "Statement of Loss" commentaries)

# **SELECTED QUARTERLY FINANCIAL INFORMATION**

The following table sets out the Corporation's selected unaudited quarterly financial information for the eight quarters ended April 30, 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.

	Q1-22	Q4-21	Q3-21	Q2-21	Q1-21	Q4-20	Q3-20	Q2-20
R&D Expenses (Net)	424	390	191	195	365	142	421	194
G&A expenses	416	472	342	186	507	136	254	361
Share-based compensation	63	112	101	49	20	74	36	44
Financial expenses	338	294	179	201	168	125	49	63
Net (loss) for the quarter	(1,241)	(1,268)	(813)	(631)	(1,060)	(477)	(760)	(662)
(Loss) per share (Basic and diluted)	(0.04)	(0.04)	(0.03)	(0.03)	(0.04)	(0.02)	(0.03)	(0.03)
EBITDA (Loss)	(888)	(951)	(611)	(413)	(862)	(323)	(682)	(570)

(See "Management's Responsibility for Financial Reporting" – "Non-IFRS Financial Measures")

# Ortho Regenerative Technologies Inc.



# Management's Discussion and Analysis for the three months ended April 30, 2021

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

R&D expenses (Net of ITCs)	<ul> <li>Net R&amp;D expenses represent gross R&amp;D expenses less ITC provisions related to these costs and to be claimed after year-end. R&amp;D expenses net of ITC provisions have fluctuated from quarter to quarter depending on the timing of work performed by our partners and suppliers as well as internal R&amp;D spending. Fees for maintenance and filing of patents have been consistent over the comparable periods.</li> <li>Net R&amp;D expenses increased 9% over the prior Q4-21 quarter. R&amp;D activities picked up late last year as the Corporation initiated CMC batch manufacturing and other IND related activities.</li> </ul>
G&A expenses	<ul> <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. G&amp;A expenses over the last 8 quarters include non-recurring charges related to changes to the senior management team, including a \$120 severance in Q2-20 to prior acting CEO.</li> <li>The Q1-21 amount includes a non-recurring \$267 salary adjustment paid to senior management for having agreed to receive non-cash remuneration between July 2019 and April 2020.</li> <li>G&amp;A expenses have also picked up since Q3-21 due to increases in IR spending.</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>
Share-Based Compensation	<ul> <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. A non-recurring grant to our Scientific Advisory Board members took place in Q4-21.</li> </ul>
Financial expenses	<ul> <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 CDU and NCDU financings closed over the last year, including \$1,644 in Q3-20, \$500 in Q4-20, \$1,060 in Q1-21, and \$3,000 in Q4-21. Each CDU has a 2-year maturity, while the NCDUs have a 3-yr maturity. Interest charges on the CDUs may go down over time as CDU holders opt to convert their debenture prior to maturity.</li> <li>Q1-22 was the first 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>
Net loss	<ul> <li>Net loss in Q4-21 increased slightly compared to prior quarter due to the relatively nominal variation in G&amp;A and R&amp;D spending. The Increase in financial expenses between Q4-21 and Q1-22 was offset by the decrease in SBC expenses.</li> <li>Going forward Ortho RTI's net loss will be 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>
EBITDA (Loss)	<ul> <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 remained flat over the prior quarter with a small 7% decrease.</li> </ul>

# LIQUIDITIES AND CAPITAL RESSOURCES

As at,			Change	
For the quarter ended	April 30, 21	April 30, 20	\$ <u>1</u>	<b>%</b> ²
Operating activities				
Net loss from operations	(1,241)	(1,060)	-181	17%
Other items not affecting cash	307	582	-275	-47%
Changes in non-cash working capital	114	18	96	533%
Cash used in operations	(820)	(460)	-360	78%
Investing activities	(32)	-	-32	100%
Financing activities	135	212	-77	-36%
Effect of foreign exchange on cash	(49)	=	-49	100%
(Decrease) increase in cash	(717)	(248)	-518	209%
Cash, beginning of period	2,379	302	2077	688%
Cash, end of period	1,613	54	1,559	2887%

<sup>1.</sup> A positive variance represents a positive impact to cash flows and a negative variance represents a negative impact to cash flows

<sup>2.</sup> Percentage change is presented in relative values





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

	Q1-22 vs Q1-21
Cash used in operations	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.
	• Cash used in operations has increased by 78% at \$820 for Q1-22 as compared to \$460 for Q1-21 period. The \$360 increase results from the \$181 increase in net loss and the \$275 decrease in items not affecting cash. Items not affecting cash decreased when compared to prior year as \$395 consulting fees were converted in CDU in Q1-21 compared to nil for Q1-22. Changes to working capital items also contributed \$114 to cash used in Q1-22 compared to only 18 for Q1-21.
Cash used in investing activities	• The Corporation used \$32 to acquire equipments during Q1-22 compared to nil for Q1-21. The equipments 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.
Cash provided by financing activities	• Financing activities contributed \$135 during Q1-22 including \$75 from a government grant to support R&D work, as well as \$60 from the exercise of warrants. This compares to \$212 for Q1-21 representing mainly \$355 for the issuance of CDUs, less \$174 for the repayment of ITC loans.
Cash, End of the period	• The Corporation ended Q1-22 with \$1,613 of cash compared to \$54 at the end of Q1-21 representing a \$1,559 increase. The series of financings completed during the past year helped increase the cash position which was used to fund operations.

### Cash, and Working Capital

As at,	April 30, 2021	January 31, 2021	Chang	ge
	\$	\$	\$ <u>1</u>	% <mark>≥</mark>
Cash	1,613	2,379	(766)	-32%
Total current assets	1,969	2,840	(871)	-31%
Accounts payables and accrued liabilities	319	291	28	10%
Convertible Debentures – short term	2,530	1,848	648	37%
Total current liabilities	3,062	2,311	751	32%
Working Capital	(1,093)	529	(1,622)	307%

<sup>1.</sup> A positive variance represents a positive impact and a negative variance represents a negative impact

Cash at the end of Q1-22 was \$1,613 as compared to \$2,379 at the end of YE-21. Despite a good cash position which results from the NCDU financing closed in Q4-21, the working capital decreased by \$1,622 between YE-21 and Q1-22. The full portion of the CDU financing closed in 2019 and 2020 are now showing as short-term liabilities compared to only the October 2019 and December 2020 portion as at YE-21.

Ortho RTI 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 it 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. Ortho RTI has enough financial resources to start its Ortho-R rotator cuff tear repair clinical program in early FY-22 (See "Overview of the Business" and "Going concern").

#### **Future financing**

As at April 30, 2021, Ortho RTI had 18.3 million warrants outstanding with an average exercise price of \$0.52. 16.65 million warrants are subject to an acceleration clauses. 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 Q1-22 and for which the acceleration clause applied, the maximum influx of cash to the Corporation would have been approximately \$8.3 million. Assuming all warrants are exercised prior to their maturity a total of \$9.6 million could be raised.

<sup>2.</sup> Percentage change is presented in relative values





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

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 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, Ortho RTI 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. An additional 3-year extension is currently under negotiation.

#### **Statement of Compliance**

The unaudited interim financial statements included in this MD&A for the quarter ending April 30, 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.

#### **Significant Accounting Policies**

#### Comparative figures restated

The comparative figures of the statement of financial position were restated to reflect a correction to the current portion of the convertible debentures as at January 31, 2021, by reclassifying an amount of \$1,848 from long-term liabilities to current liabilities.