

Management's Discussion and Analysis for the three months ended April 30, 2022

(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 first quarter of our 2023 fiscal year ended on April 30, 2022 and compares those of the same period in 2022 fiscal year. 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. This report was reviewed by the Corporation's Audit Committee and approved by ORTI's Board of Directors on June 20, 2022. This document should be read in conjunction with the unaudited financial statements and notes thereto for the first quarter of our 2023 fiscal year ended on April 30, 2022, which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). Further information about Ortho Regenerative Technologies Inc., is available online on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

Unless otherwise noted, all amounts are presented in thousands of Canadian dollars, except for share and per share amounts.

#### 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 first quarter ended on April 30, 2022, the Corporation incurred a net loss of \$0.85 million, and used cash in operations of \$0.7 million. As at the end of the first quarter of fiscal year 2023, the Corporation had a working capital surplus of \$0.6 million. Consequently, 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 unaudited financial statements as at and for the quarter ended April 30, 2022, 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. Elective surgeries levels are key to ensure enrollment in our US Phase I/II clinical trial on rotator cuff tear repair. Based on recent interactions with the clinical centers involved in the clinical trial, scheduling and rate of elective surgeries are back to pre-pandemic levels and consequently should not impact patient enrollment.

## **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 Loss", 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 Loss is defined as net loss before (i) provision for (recovery of) income taxes; (iii) 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",





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"continue" or similar terminology. Forward looking information is subject to various known and unknown risks and uncertainties, many of 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 &	<u>Financial</u>	Corporate & Op	Corporate & Operations		
CDU	Convertible Debenture Units	API	Active Pharmaceutical Ingredient		
EBITDA (L)	EBITDA Loss	CMC	Chemistry Manufacturing and Controls		
FV	Fair Value	cGMP	current Good Manufacturing Practice		
FY	Fiscal Year	CMO	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		
NCDUs	Non-Convertible Debenture Units	MCRA	MCRA, LLC, a US based orthopedic specialty CRO		
Q1-23	First quarter FY-23	MRI	Magnetic Resonance Imaging		
Q4-22	Fourth quarter FY-22	MTA	Material Transfer Agreement		
Q3-22	Third quarter FY-22	ORT	Ortho Regenerative Technologies Inc.		
Q2-22	Second quarter FY-22	ORTHO-C	Proprietary biopolymer for Articular Cartilage repair		
Q1-22	First quarter FY-22	ORTHO-M	Proprietary biopolymer for Proprietary Biopolymer for		
Q4-21	Fourth quarter FY-21		Meniscus repair		
Q3-21	Third quarter FY-21	ORTHO-R	Proprietary biopolymer for Rotator cuff repair		
Q2-21	Second quarter FY-21	ORTHO-V	Proprietary biopolymer for Osteoarthritis healing		
SR&ED	Scientific Research and Experimental	OTCQB	US over-the-counter venture trading market		
	Development Expenses	Polytechnique	Ecole Polytechnique de Montreal		
R&D	Research and Development	PRP	Platelet-rich plasma		
YTD	Year to date	Pre-RFD	Pre-Request for Designation		
YE	Year-end				
W/C	Working Capital, defined as short-term assets less short-term liabilities				

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

ORT is a clinical stage drug biotech company 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 and its wholly owned US subsidiary, OR4102022 Inc. has been incorporated on April 20, 2022 (See "Subsequent Events") and is located at 12 Penns Trail in Newtown, Pennsylvania, USA. 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 "ORTF".

The Corporation is developing products in the regenerative medicine market, one of the most dynamic and promising sectors of the health care industry.

## **Regenerative Medicine Overview**

The concept of regenerative medicine is to provide us with tools to return anatomy and physiology to a more normal appearance and behaviour. Although there are many definitions, of what constitutes regenerative medicine, the following is succinct:

Regenerative Medicine is an emerging interdisciplinary field of research and clinical applications focused on the repair, replacement or regeneration of cells, tissues or organs to restore impaired function resulting from any cause, including congenital defects, disease, trauma and aging. It uses a combination of several technological approaches that moves it beyond traditional transplantation and replacement therapies. These approaches may include, but are not limited to, the use of soluble molecules, gene therapy, stem cell transplantation, tissue engineering and the reprogramming of cell and tissue types.

Combinations of these approaches can 1) improve the natural healing process in areas of the body it is needed most, 2) take over the function of a permanently damaged organ, 3) heal or repair a damaged organ or tissue, or 4) deliver healing "accelerators" chemicals that might inspire repair to specific damaged areas of the body.

Regenerative medicine is a relatively new and rapidly expanding field that brings together experts in biology, chemistry, materials and computer science, engineering, genetics, robotics, and other fields to find solutions to some of the most challenging medical problems faced by humankind. We believe ORTHO is at the forefront of this rapidly expanding field.



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The Global Regenerative Medicine Market was a \$US9B market in 2021 and is projected to grow at 22.8%CAGR through 2030. It is one of the most dynamic markets in medicine today. The musculoskeletal and wound healing segment accounted for about 60% share of the regenerative medicine market in 2021. Cell therapies are used in the treatment of musculoskeletal diseases such as bone tissue replacement, cartilage, tendon, and ligament repair and replacement.

Regenerative medicine is applicable in cardiovascular, oncology, dermatology, musculoskeletal, wound healing, ophthalmology, neurology, and others. The musculoskeletal application segment accounted for the largest share in 2021, whereas cardiovascular is expected to be the fastest-growing segment, registering a CAGR of 24.3% during the forecast period (2022-2030).

#### **Problem & Solution**

The delivery of a tissue scaffold, cellular or molecular therapy or any combination thereof makes a fundamental assumption; that the substance(s) will stay where they were placed and function as desired; if they wander off-target, the desired enhanced healing might not occur and furthermore, the potential exists for off-target effects.

Providing a reliable, biologically safe transport mechanism that would allow the targeted body system to receive the regenerative material to aid in body system repair is, therefore, a mission-critical goal and a problem that requires solving.

Ortho Regenerative Technologies (ORT) has acquired just such a solution from the Polytechnique at the University of Montreal. Our Patented **Drug/ Biologic/ Combination** technology platform, is a muco-adhesive CHITOSAN based biopolymer matrix, specifically designed to be combined with biologics such as Platelet-Rich Plasma (PRP) or Bone Marrow Aspirate Concentrate (BMAC), to augment and accelerate the regeneration of new tissue in various potential indications.

## **BUSINESS STRATEGY**

- 1. Perform Rotator Cuff Repair proof of concept phase I/II clinical trial program to establish regenerative platform
- 2. Leverage Polytechnique partnership to obtain non-dilutive grants to drive proof of concept in multiple potential indications
- Leverage our proprietary platform beyond orthopedic applications by seeking R&D and/or development partners for each high potential application
  - Leverage strong global method and composition patents
  - Leverage initial IND from FDA to initiate multiple development programs
- 4. Seek regulatory clearance in other high value jurisdictions

# 1. Perform Rotator Cuff Repair proof of concept phase I/II clinical trial program to establish regenerative platform

**ORTHO R** is formulated and designed to improve the healing of occupational and sports related injuries to tendons, meniscus, and ligaments.



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 an injectable combination of the chitosan scaffold and the PRP-biologic, and an FDA designated bioactive implant that coagulate after implantation. 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;



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- (ii) biopolymer-PRP mixtures having paste-like handling properties desired by surgeons;
- (iii) biopolymer-PRP mixtures that coagulate rapidly to form soft tissue-adherent Drug-Biologics hybrid 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 polymer-biologics hybrid mix, designated as drug/biologic combination product by the FDA, but may be considered a medical device by other regulatory jurisdictions, can be directly applied at the site of injury by a surgeon during a routine operative procedure without significantly extending the time of surgery and without further intervention. A US FDA IND was granted in December 2021, to start a Phase I/II Rotator Cuff Tear Repair clinical trial at 10 US sites.

The use of ORTHO-R as an adjunct to standard of care suturing techniques produced promising histological findings in small and large animal experimental models, which is hoped 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.

Market Opportunity: (Source:Pearl Diver HealthCare Research, iData Research.) for first clinical application

Close to 700K shoulder rotator cuff repairs are performed in North America every year with an unfortunate 20% to 90% failure rate. ORT has already initiated its FDA designated Phase I/II study giving it the regulatory lead in the US for launching the first FDA approved drug/biologic combination for augmenting the performance of the standard of care surgical shoulder cuff repair.

The orthopedic and sports medicine soft tissue repair market is a \$11B+ global market. The ORTHO-R product is targeting the following soft tissue repair indications: rotator cuff Tear repair: 4M injuries and 700K surgeries/year (50%+ failure rate) in USA alone, Tendinopathy, 11M injuries/year, and Meniscus Tear repair: 1.2M injuries/year and 200K+ surgeries/year (40% failure rate) in USA alone. Standard of care for these injuries is surgery alone. The orthopedic community are looking for better treatments to improve patient outcomes and reduce procedure failure rate.

This market opportunity is further enhanced by the fact that surgeons all over the world know that soft tissue such as ligaments, tendons and meniscus are not well vascularized and thus when repaired with the standard of care (sutures, anchors, and staples) results in healing principally with scar tissue which is more fragile and susceptible to re-tear than native tissue. Given the believe by many that platelet rich plasma (PRP) improves the quality of tissue healing, surgeons have vocalized a desire to find a way to make PRP resident to the surgical repair site, so that the PRP can trigger the tissue repair cascade to these troublesome non-vascularized soft tissues. Surgeons have been using PRP for over a decade but are frustrated by the inability for the PRP alone to establish residency on the surgical repair site due to its highly liquid nature. ORTHO-R is specifically designed to overcome the residency issue due to its unique and patented composition. Therefore, once approved, a ready-made and very large market can be rapidly satisfied thus reducing go to market investment by the company, development partner or acquirer of our technology.

In November 2017, FDA published a memo to the regenerative medicine industry stating that orthopedic regenerative products now require a Biologics License Application (BLA) from the Center for Biologics Evaluation and Research (CBER) at FDA. According to the FDA memo: "Regenerative medicine therapies have not been approved for the treatment of any orthopedic condition, such as osteoarthritis, tendonitis, disc disease, tennis elbow, back pain, hip pain, knee pain, neck pain, or shoulder pain". Therefore, a Biologic License is required by ORT, and thus comprehensive pre-clinical and clinical trials are required to demonstrate safety and effectiveness of orthopedic regenerative treatments. ORT coincidently had already begun its pre-clinical work at that time and have already obtained an IND in December 2021. We believe that ORT is therefore in the regulatory lead to bring the first biologic licensed drug/biologic orthopedic regenerative medicine to the market.

## **ORTHO-R®: Key points of differentiation**

Unlike other natural biopolymer matrix such as Hyaluronic Acid (HA) or Collagen, the chitosan natural biopolymer molecules are positively charged and therefore are muco-adhesive (sticky) to the negatively charged soft tissues of the human body (tendons, ligaments, meniscus). Characteristics related to the electrostatic binding of the combination product, resulting modification of cell function, slowing of blood clot retraction and extended release of growth factors compared to PRP alone provided justification for classification of the product as a drug. It is therefore a perfect matrix system for biologics such as PRP, used in various musculoskeletal injury conditions. ORTHO-R has a fast coagulation onset, and with its muco-adhesive feature offer the unique benefit of significantly increasing the in-situ residency time of PRP implants from less than 24 hours for PRP alone to up to 6 weeks for ORTHO-R chitosan-PRP drug/biologic combination product, allowing PRP to contribute to the normal healing cascade. ORTHO-R becomes the desired solution option for the orthopedic soft tissue repair community, by addressing the actual limited clinical outcomes resulting from short lived / washed out use of PRP alone in clinical orthopedic practice.



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## **Preclinical:**

In Q4-21, we successfully completed the preclinical pivotal study safety and clinical histology analysis, statistical analysis and final report. The final study 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, improved 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

## **Manufacturing & CMC:**

Our cGMP clinical lot production has been successfully completed earlier in FY-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 funded by a non-dilutive grant, expected to be initiated in FY-23 shortly after the commencement of our Phase I/II Rotator cuff repair trial.

## Regulatory:

During FY-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, and the generation of further intellectual property

#### Clinical:

The Phase I/II clinical trial status is as follows:

- Our Investigational New Drug (IND) application to the FDA was submitted on April 6, 2021 and granted on December 10, 2021.
- 10 US based clinical sites have been selected for the trial.
- 7 clinical sites have been fully contracted and the last 3 sites are currently completing their contract and budget negotiations.
- 7 sites have been initiated and are actively recruiting patients. We expect to initiate one more site before the end of Q2-23 and the last two sites in Q3-23.
- Patient screening and enrollment has begun, and we expect to randomize our first patients in Q2-23.
- Phase I part of the study is expected to be completed in Q3-23
- Completion of the Phase II recruitment is expected in Q4-23/Q1-24 depending on sites' enrolment rate.
- Follow up and individual patient assessment and Phase II scoring will take place 12 months after surgery.

# 2. Leverage Polytechnique partnership to obtain non-dilutive grants to drive proof of concept in multiple potential indications

ORT's has received\* and is seeking\*\* non-dilutive research grants through its partnership with Polytechnique

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 was filed on April 6 <sup>th</sup> , 2022, with the FDA to obtain approval to initiate a 78 patient Phase I/II clinical trial to test Ortho-R in combination with PRP in the repair of rotator cuff tears as an adjunct to standard of care surgery, versus standard of care surgery alone. The IND was granted in December 2022. <u>See ORTHO-R Clinical Trial update below</u>
ORTHO-M*	Pre-Clinical	Meniscus	Testing the efficacy of ORTHO-M/PRP Drug-Biologic Implant formulation, for meniscus repair. Efficacy of our product has already been demonstrated in an 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 Q3-23. Human clinical trials would then follow. \$500K grant obtained



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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.
ORTHO-T**	Feasibility	Tendinopathy	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 help with tendon healing and regeneration. \$4M grant being submitted in Q2-23 (Calendar)

# 3. Drive development of our proprietary platform beyond orthopedic applications by seeking R&D and/or development partners for each high potential application

## **Our Proprietary Technology Platform Can Be So Much More**

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

The functionality of the chitosan framework could potentially be used in numerous other applications which could potentially address high unmet needs with profound clinical consequences.

We will also investigate combining ORT's patented chitosan framework with targeted delivery of numerous autologous and synthetic therapeutics, either developed internally, licensed, or secured through strategic partnerships with biologic and/or pharma companies.

We will determine the highest value programs through consultation with our scientific and business advisory board and find R&D or development partners for the highest value projects

## 4. Seek regulatory clearance in other high value jurisdictions

ORT will seek regulatory clearances in Canada where the ORTHO-R product may be considered a medical device

ORT will seek advice on the regulatory pathway for our platform in Australia and Europe.

# **Overall Value Proposition**

Drug/Biologic PRP Combination

## **Technology Platform**

- o Proprietary, novel, multi-indications, second generation, de-risked platform
- Strong intellectual property protection in three patent families
- o Potentially addresses significant unmet medical need in large regenerative medicine market
- o First solution to increase residence time to augment regeneration of new tissue
- Validated mode of action, safe and easy to use solution,
- o Rapid coagulation and avoids shrinkage of implant, potentially adheres to multiple tissues
- Demonstrated efficacy in large animal model (decreased tendon gap & improved bone structure)

## ORTHO-R: Unique Drug / Biologics / Device Combination Product

- o In the US regulatory lead as the first PRP based drub/biologic product in human trials
- o Target U.S. market first with clear regulatory pathway from FDA (IND to BLA)
- o Potentially simpler regulatory pathways in major markets outside the US
- o Inexpensive to manufacture
- o Uses autologous PRP which can be sourced quickly and easily during surgery
- Lyophilized chitosan provides long shelf life

## **Great Value Creation & Exit Potential**

- Phase I/II clinical trial initiated with first patients imminent.
- Multiple material milestones expected over next 12-24 months including completion of phase I/II clinical trial.
- NASDAQ listing to be considered for first half of 2023 calendar year
- Multiple regenerative medicine applications



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- Experienced management, Board and Clinical Advisory Board with history of value creation
- Low market valuation vs. industry peers
- Sufficient capital raised to start phase I/II study in rotator cuff indication

## **Intellectual Property**

ORT is the owner of 3 patent families. Our patent portfolio includes the following:

Family	Description	Patent Status
<u>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.	<ul><li>Issued – Globally</li><li>Expiry - 2030</li></ul>
<u>No.2</u> :	Freeze-dried polymer compositions for mixing with platelet rich plasma to form implants for tissue repair or compositions for therapeutic intra-articular injection.	<ul><li>Issued – Globally</li><li>Expiry - 2035</li></ul>
<u>No.3</u> :	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.	<ul> <li>Issued/Allowance pending – Globally</li> <li>Expiry – 2035 / TBD</li> </ul>

## Q1-2023 CORPORATE HIGHLIGHTS (February 1, 2022 to April 30, 2022)

- On March 14, 2022, Claude Leduc, CEO of Ortho announced his retirement. On the same date, the Corporation announced the hiring of Philippe Deschamps as its new President and CEO with Mr. Leduc agreeing to assist in the transition. Mr. Deschamps is a seasoned public company CEO focused on the healthcare market for the past 35 years and the last 20 years as CEO of 3 healthcare companies. Mr. Deschamps' most relevant experience was as co-founder of Helius Medical Technologies Inc. where he guided the company from the Canadian Securities Exchange to the NASDAQ and raised over a \$100M in the process. Mr. Deschamps' initial priorities will be to drive the advancement of the Ortho-R Phase I/II clinical trial for rotator cuff repair, uncover other potential uses for Ortho's core proprietary assets, and focus on investors relation activities in anticipation of the Corporation's upcoming clinical and corporate milestones.
- On April 5, 2022, the Corporation announced the closing of an oversubscribed non-brokered private placement of units for \$3.2 million (the "Private Placement"), with approximately \$560,000 of Insiders' subscriptions. The Company issued 16,000,000 Units at a price of \$0.20 per Unit for total gross proceeds of \$3.2 million of which an amount \$2.7 million was received in cash, an amount of \$0.2 million was issued as a replacement to convertible notes issued in December 2021 and the balance in compensation for accounts payable and accrued liabilities. Each Unit consists of one (1) Class A share of the Company (each, a "Common share") and one Common share purchase warrant (each a "Warrant"). Each Warrant will be exercisable into one (1) Share in the capital of the Company at the price of \$0.35 per Warrant Share for a period of 24 months from closing. If the closing price of the Shares is greater or equal to \$0.50 for ten (10) consecutive trading days, the Company may give notice to the Warrant holder, at any time after the statutory 4-month hold period, 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.

As a result of the closing of the Private Placement, Convertible Debentures bearing interest of 10% per annum and maturing on May 1, 2023 were amended such that their conversion price was reduced from \$0.30 to \$0.20 to match the purchase price of Units under this Private Placement. In addition, the exercise price of the 1,075,000 warrants and the 20,625 Finder's warrants issued on December 10, 2021 issued in connection with the Convertible Note Units financing were reduced from \$0.50 to \$0.35 to match the exercise price of the Warrants comprised in the Units sold under this Private Placement.

- On April 8, 2022 (the "Date of Grant") the Corporation granted 2,000,000 stock purchase options (the "Options") and 551,938 Restricted
  Stock Units ("RSU") to its newly hired CEO, Philippe Deschamps. Half of the Options and RSU's will vest annually and equally over the
  first 3 years following the Date of Grant. The balance of the Options and RSU's will vest based on achievements of predetermined
  operational and corporate milestones.
- On April 20, 2022, the Corporation created a wholly owned subsidiary in the United States called OR4102022 Inc. This subsidiary was created in the State of Delaware where business case law is most sophisticated. The subsidiary was also registered in Pennsylvania (PA) since the CEO, Philippe Deschamps, will operate the Corporation primarily from the US office located at 12 Penns Trail, Newtown in PA. The new subsidiary also became the sponsor of the ORTHO R Phase I/II clinical trial being performed in the US.



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## Events Subsequent to the end of the quarter

- On May 1, 2022, the Corporation received a method and composition patent from the US Patent Office and received notice issue from
  Canada and European patent offices for the composition and method patents on one of its key patents for its freeze-dried polymer
  compositions for mixing with platelet rich plasma to form implants for tissue repair or compositions for therapeutic intra-articular
  injection.
- On May 4, 2022, the Corporation announced that the United States Patent and Trademark Office (the "USPTO") had issued a patent related to the Company's ORTHO-R soft tissue repair platform. The issued patent, titled, "Freeze-Dried Polymer Compositions for mixing with platelet rich plasma to form implants for tissue repair and/or composition for therapeutic intraarticular injection" (US Patent Application No. U.S. 11,285,100 B2) provides broad protection for both the composition and the method of use of our ORTHO R technology. New patent issued by USPTO to protect core IP until 2035 and positions the Corporation as leading player in the dynamic regenerative medicine market. The patent enables delivery of PRP in soft tissue repair surgery in a proprietary way.
- On May 19, 2022, the Corporation issued 500,000 warrants with an exercise price of \$0.35 per Common Share and expiring April 30,
   2023 as compensation to non-related parties providing social media support and other corporate services.
- On May 26, 2022, the Corporation announced that it had received, through its partnership with Polytechnique Montreal, a \$0.5 million nondilutive grant from Axelys, to advance the development of its second technology platform indication, ORTHO-M, for meniscus repair.
- On June 13, 2022, the Corporation announced that patient recruitment for its Phase I/II Clinical trial for testing Ortho-R for rotator cuff repair had been initiated with six of the ten sites actively recruiting patients.





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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, 2022 unaudited financial statements.

			Chang	ie
	Q1-23	Q1-22	\$ <sup>1</sup>	% <sup>2</sup>
Expenses				
R&D	663	402	261	65%
G&A	567	438	129	29%
Share-based compensation	42	63	(21)	-33%
Financial	351	339	12	4%
Total Expenses	1,623	1,242	381	31%
Fair Value adjustment embedded derivative	(734)	-	(734)	-100%
Fair Value adjustment on warrants	(39)	-	(39)	-100%
Net (Loss) and Comprehensive loss	(850)	(1,242)	392	-32%
(Loss) per share				
Weighted average number of shares outstanding	39,552,285	34,872,899	4,679,386	13%
Basic and diluted loss per share	0.02	0.04	(0.02)	-50%

<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 Q1-23 as compared to Q1-22.

			Chang	ge
	Q1-23	Q1-22	<b>\$</b> <sup>1</sup>	% <sup>2</sup>
Net loss	(850)	(1,242)	392	-32%
Add (deduct)				
Financial Expense	351	339	12	4%
Fair Value adjustment embedded derivative	(734)	-	(734)	-100%
Total Expenses	(39)	-	(39)	-100%
Depreciation	7	7	-	0%
Amortization	8	8	-	0%
EBITDA (L)	(1,257)	(888)	(366)	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

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

	Q1-23 vs Q1-22
Revenues	ORTI is a clinical stage company. There were no revenues generated during each of Q1-23 and Q1-22.
R&D expenses	• 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 are presented net of R&D tax credits (ITCs) recoverable from the provincial government for Scientific Research and Experimental Development (SR&ED) programs, and net of government grants.
	• R&D expenses in Q1-23 increased over Q1-22 at \$663 compared to \$402, representing a 65% increase. During Q1-23, the Corporation increased its R&D activities after receiving in Q4-22, the clearance by the FDA of its IND application to commence its Phase I/II clinical study for testing Ortho-R for rotator cuff repair. Such activities included mainly expenses related to prepare and activate all 10 US sites participating in the study. R&D expenses also included site fees, and other auxiliary costs required to get the sites ready for enrollment and screening patients. In Q1-22, the R&D costs include the finalization of the Clinical batch manufacturing and some pre-IND costs.
	<ul> <li>R&amp;D Costs are presented net of ITCs representing R&amp;D tax credits recovered from the provincial government for SR&amp;ED programs. ITCs accruals for Q1-23 were \$62 or 8% of R&amp;D costs, compared to \$\$33 and 8% for</li> </ul>

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





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

	the Q1-22 period. The Corporation will favour Quebec based suppliers where possible in order to claim SR&ED refundable credits and reduce the net costs of performing its R&D programs.  • During FY-22, the Corporation secured a \$75 grant for conducting its R&D activities. The grant is to be amortized over the term of the 2-yr agreement. \$12 was recognized during Q1-23 compared to \$6 in Q1-22.
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 Q1-23 increase over Q1-22 at \$567 compared to \$438 representing a 29% variance. The increase includes some additional charges to perform the year-end audit, as well as salary charges related to the addition of a new CEO, Phil Deschamps, and the cost of retaining the prior CEO during a transition period which ended at the end of Q1-23. The departing CEO will be receiving a severance to be paid over the coming year.</li> </ul>
Share-based compensation (SBC)	<ul> <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>
Financial expenses	<ul> <li>Financial expenses include interest on loans, non-convertible and convertible debentures, as well as effective interest on debentures as well as foreign exchange gain or loss.</li> <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 2022, 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 as well as a \$1.1 million bridge financing in Q4-22. All these transactions have impacted the financial expenses.</li> <li>A \$0.2 million portion of the December 2022 bridge financing was converted into the \$3.2 million Private Placement financing ("April 2022 PIPE"), thus reducing the financial expenses going forward.</li> <li>Financial expenses have increased slightly in Q1-23 compared to Q1-22 at \$351 compared to \$339 representing a 4% 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 Q1-22 which was outstanding for the full quarter in Q1-23 compared to only a few weeks in Q1-22.</li> <li>The increase in financial expenses for Q1-23 include a \$24 gain on foreign exchange transactions, as compared to a \$38 loss for Q1-22.</li> </ul>
Fair Value of Embedded Derivative	<ul> <li>On July 19, 2022, the Corporation announced the amendment of three series of CDUs to extend their respective maturity dates. (See "Balance Sheet Highlights" for more details).</li> <li>An Embedded derivative comprised of the conversion options classified as liability was created following the amendment of the CDUs. Starting Q4-22, any change in the Fair Value of the Conversion Option of the CDUs ("FVCO") has to be recorded as a financial expense.</li> <li>During Q1-23, the change in the FVCO, led to a gain of \$0.7 million. There was no FVCO adjustments required for Q1-22 considering the embedded derivative was created in Q3-22.</li> <li>The change in FVCO recorded in Q1-23 was mainly due to 1) the change in share price between the end of Q4-22 and Q1-23, as well as 2) the change in the conversion price of the CDUs which was triggered by the terms of the April 2022 PIPE. As a result of the April 2023 PIPE, the conversion price of all 3 series of CDUs maturing May 1, 2023 has been reduced from \$0.30 to \$0.20.</li> </ul>
Fair Value adjustments on warrants	<ul> <li>The terms of the warrants issued as part of the December 2022 Bridge financing led to the creation of a warrant liability ("FVAW"). Until the warrants are exercised or expire, a fair value adjustment to the warrants will be recorded quarterly to reflect the change in the warrant liability.</li> <li>During Q1-23, the Corporation recorded a gain on revaluation of their related Warrants' fair value of \$39. This adjustment mainly results from the decrease in the Corporation's share price between the end of Q4-22 and Q1-23 net of the impact of the exercise price amendment that took place as a result of the April 2023 PIPE. (See note 11a to our Q1-23 Financial Statements).</li> </ul>
Net Loss for the period.	• Net loss decreased by 32% between Q1-22 and Q1-23 at \$0.85 million compared to \$1,2 million. The \$0.4 million decrease in net loss was primarily due to the \$0.8 million combined gain of revaluation of the CDU embedded derivative and warrant liability, which more than offset the increase in R&D and G&A expenses for the quarter.
EBITDA (L)	• 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.





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

• After eliminating the impact of the financial expenses, as well as depreciation, and amortization, but also after eliminating the impact of the combined gain on revaluation of the CDU embedded derivative and warrant liability, our EBITDA loss during Q1-23 was \$1.3 million compared to \$0.9 million for Q1-22, representing a 41% increase.

## **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, 2022.

As at,	April 30, 2022	31-Jan-21	Change		
	\$	\$	<b>\$</b> <sup>1</sup>	<b>%</b> <sup>2</sup>	
Cash	2,190	313	1,877	600%	
Prepaids and deposits	131	120	11	9%	
Intangible Assets	324	332	-8	-2%	
Total assets	3,015	1,123	1,892	168%	
Trade accounts payable and accrued liabilities	1,078	607	471	78%	
Convertible notes	766	934	-168	100%	
Convertible Debentures	2,454	2,387	67	3%	
Non-Convertible Debentures	2,421	2,349	72	3%	
Warrants classified as liability	100	139	-39	100%	
Embedded derivative	848	1,582	-734	100%	
Total liabilities	7,842	8,227	-385	-5%	
Common shares	10,455	7,891	2,564	32%	
Warrants	2,293	1,828	465	25%	
Contributed surplus	2,202	2,104	98	5%	
Deficit	(19,777)	(18,927)	-850	4%	

- 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
- 3. 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, 2022, by reclassifying an amount of \$1,848 from long-term liabilities to current liabilities.

Selected items	Q1-23 vs YE-22
Cash	• Cash at the end of Q1-23 was \$2.2 million compared to \$0.3 million at the start of the fiscal year. The increase in cash takes into consideration the net impact of the April 2022 PIPE, which generated gross proceeds of \$3.2 million and net proceeds of \$2.7 million less liquidities required to fund operations during the quarter.
Prepaids and deposits	No material change since year-end 2022.
Intangible Asset	• Intangible assets reflect the net book value of our patents and biopolymer technology acquired from Polyvalor. The nominal reduction between YE-22 and Q1-23 results from amortization charges which were not offset by new investments.
Total assets	• The decrease in cash during the quarter led to a 168% increase in our total assets between the end of FY-22 and Q1-23.
Trade payables and accrued liabilities	<ul> <li>Trade accounts payables and accrued liabilities have increased by \$0.5 million during Q1-23 following the increase in R&amp;D activities that took place during the quarter.</li> </ul>
Convertible Notes	• Convertible notes were issued as part of the bridge financing announced December 2022. \$0.2 million of these notes have been converted into the April 2022 PIPE (See "Subsequent events"). Unless previously converted, the balance is due at maturity in December 2022. The reduction since the start of the fiscal year takes into consideration the \$0.2 million of notes converted into the April 2022 PIPE, as well as accretion expense for the period.
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.</li> <li>The nominal increase between the end of FY-22 and Q1-23 represents accretion expense of \$0.1 million.</li> </ul>





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

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 \$0.1 million between YE-22 and Q1-23 represents accretion expense for the Q1-23 period.
Warrants classified as liability	• This item represents the \$0.1 million Fair Value of the warrants issued as part of the December 2022 bridge financing less the gain on reevaluation of the warrants between the date of issuance and Q1-23. (See "Financial Statements - note 11b").
Embedded Derivative	<ul> <li>In July 2022, a \$1.2 million embedded derivative representing the related conversion options was created following the amendment of the CDUs.</li> <li>Any change in the Fair Value of the Conversion Option of the CDUs ("FVCO") is recorded as a financial expense in the statements of loss, as a gain or loss on embedded derivative related to CDUs.</li> <li>Changes to the FVCO takes 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> <li>During Q1-23, the FVCO decreased by \$0.7 million. The change in FVCO takes into account the revaluation that took place as a result of the terms of the April 22 PIPE which led to a reduction of the conversion price of the CDU.</li> </ul>
Total Liabilities	• Total liabilities have decreased between YE-22 and Q1-23. The \$0.5 million variation included a \$0.5 million increase in payables and accrued liability but offset by the \$0.2 million reduction of Convertible notes issued in December 2022, and the combined \$0.8 million gain on revaluation of the warrant liability and CDU embedded derivative.
Common Shares	• Common shares have increase by \$2.6 million mainly as a result of the April 2022 PIPE net of share issue costs.
Warrants	• Warrants increased by \$0.5 million mainly as a result of the warrants issued as part of the April 2022 PIPE net of the allocation of share issue costs, less the impact of expired warrants.
Contributed Surplus	• The contributed surplus increased by \$0.1 million as a result of share-based compensation expense and the expiry of warrants.
Deficit	• Increase reflects the performance of the Corporation during Q1-23. (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, 2022. 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.

	Q1-23	Q4-22	Q3-22	Q2-22	Q1-22	Q4-21	Q3-21	Q2-21
R&D Expenses (Net)	663	415	591	141	402	390	191	195
G&A expenses	567	309	357	367	438	472	342	186
Share-based compensation	42	67	43	64	63	112	101	49
Financial expenses (income)	351	370	266	332	339	294	179	201
Fair Value adjustment embedded derivative	(734)	(279)	667	-	-	-	-	-
Fair Value adjustment on warrants	(39)	(31)	-	-	-	-	-	-
Net Loss	(850)	(851)	(1,924)	(904)	(1,242)	(1,268)	(813)	(631)
Loss per share (Basic and diluted):	(0.02)	(0.02)	(0.06)	(0.03)	(0.04)	(0.04)	(0.03)	(0.03)
EBITDA (Loss)	(1,254)	(773)	(973)	(413)	(888)	(955)	(611)	(413)

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

Notes	Valuable information
R&D expenses (Net of ITCs and grants)	• Net R&D expenses increased 60% over the prior Q4-22 quarter. R&D activities have accelerated in Q1-23 following the IND grant received by the FDA in Q4-22 to commence the Phase I/II trial for testing Ortho-R for rotator cuff repair. R&D expenses in Q1-22 and Q4-22 picked up over prior quarters as the Corporation performed its CMC batch manufacturing.
G&A expenses	• G&A expenses have increased in Q1-23 compared to the prior quarter and reflected the impact of senior management changes that took place during the quarter. IR activities also increased during the quarter and contributed to the closing of the April 2022 PIPE. Other expenses, such as rent, insurance, and office expenses, have been relatively stable and had no significant impact on the overall spending. We expect G&A to be stable for the coming quarters.





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

Share-Based	• Share-based compensation fluctuates as a results of staff changes, and due to the timing of expense recognition				
Compensation	associated with the vesting of the options issued.				
Financial expenses	<ul> <li>Financial expenses have increased starting Q4-21 following the implementation of the \$3.0 million NCDU.</li> <li>Q1-23 financial expenses were slightly lower than Q4-22 due to FX gains recorder during the quarter.</li> <li>The increase in Q4-22 related to the issuance of Convertible Notes as part of the December 2021 Bridge Financing – \$0.2 million of which has been converted into the April 2022 private placement.</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>ITC loans have been repaid in Q4-21.</li> </ul>				
FV adjustment of embedded derivative	• The changes to the terms of the CDU conversion price as well as the variation in share price during the last quarters has led to respective changes in the Fair Value of the Conversion Option of the CDUs ("FVCO") representing \$0.7 million decrease in Q1-23, \$0.3 million decrease in Q4-22 and \$0.7 million increase in Q3-22. There was no embedded derivative prior to Q3-22.				
Fair Value adjustments on warrants	<ul> <li>The Fair value adjustments to the warrants ("FVAW") issued as part of the December 2021 bridge financing was recorded as a liability in Q4-22 (See "Balance Sheet section").</li> <li>Going forward the change in FV between the end of each quarter will be recorded as a gain or expense quarterly going forward until the warrants are exercised or expired.</li> <li>The change in FVAW led to a nominal gain for each of Q4-22, and Q1-23.</li> </ul>				
Net loss	<ul> <li>Net loss in Q1-23 was similar as Q4-22 as the increase in R&amp;D and G&amp;A was offset by the combined gain revaluation of the FVCO and FVAW.</li> <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 Q1-23 was offset by the decrease in SBC expenses.</li> <li>Going forward ORTI 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) in Q1-23 increased over Q4-22 as R&amp;D activities picked up following the IND grant in December 2022. Fluctuations over prior quarter were directly related to variations in R&amp;D and G&amp;A spendings described above.</li> </ul>				

# LIQUIDITIES AND CAPITAL RESSOURCES

		30-Apr-21	Change	
For the quarter ended on,	30-Apr-22		<b>\$</b> 1	<b>%</b> <sup>2</sup>
Operating activities:				
Net loss from operations	(850)	(1,242)	392	-32%
Other items not affecting cash	(270)	297	(567)	-191%
Changes in non-cash working capital	399	124	275	222%
Cash used in operations	(721)	(821)	100	-12%
Investing activities:				
Cash used in investing activities	-	(32)	32	100%
Financing activities:				
Cash provided by financing activities	2,571	135	2,436	1804%
Cash, beginning of period	313	2,379	(2,066)	-87%
(Decrease) increase in cash	1,850	(718)	2,568	-358%
Effect of foreign exchange on cash	27	(48)	<i>7</i> 5	-156%
Cash, end of period	2,190	1,613	577	36%

- 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

	Q1-23 vs Q1-22
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.





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

	• Cash used in operations was \$0.7 million for Q1-23 as compared to \$0.8 million for Q1-22 period, representing a \$0.1 million decrease. The decrease results from the \$0.4 million increase in net loss and a \$0.6 million decrease in items not affecting cash which captured the combined \$0.8 million gains on fair value adjustments to the CDU embedded derivative and warrant liability, as well as \$0.3 million impact for converting consulting fees and payables into the April 2022 PIPE. Cash used in operations in Q1-23 also benefited from a \$0.4 million positive change in non-cash working capital items including a \$0.3 million in payables.
Cash used in investing activities	No investments during Q1-23, compared to nominal investment in Q1-22.
Cash provided by financing activities	• Financing activities generated \$2.6 million during the quarter representing the net impact of the April 2022 PIPE compared to \$0.1 million in Q1-22 which included nominal proceeds from the exercise of warrants as well as a \$0.1 million government grant to support R&D work.
Cash, End of the period	• The Corporation ended Q1-23 with \$2.2 million of cash compared to \$1.6 million at the end of Q1-22 representing a \$0.6 million increase. Cash increased by \$1.9 million during Q1-23 as a result of the April 2-22 PIPE compared to a \$0.7 million decrease in Q1-22 as the Corporation mainly used its liquidities to fund its operations.

## Cash, and Working Capital

			Change	
As at,	30-Apr-22	31-Jan-22	<b>\$</b> <sup>1</sup>	<b>%</b> <sup>2</sup>
Cash	2,190	313	1,877	600%
Total current assets	2,629	722	1,907	264%
Accounts payables and accrued liabilities	1,078	607	471	78%
Convertible Notes	766	934	(168)	100%
Warrants presented as a liability	100	139	(39)	100%
Total current liabilities	2,079	1,869	210	11%
Working Capital	550	(1,147)	1,697	-148%

- 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 Q1-23 was \$2.2 million as compared to \$0.3 million at the end of YE-22 representing a \$1.9 million increase. During Q1-23, working capital also improved by a similar amount with a \$1.7 million increase.

The Corporation will continue to use its liquidities to fund its operations including its primary objective of advancing its first Phase I/II human trial on Ortho-R for rotator cuff repair. Following delays in FY-22 due to our interaction with the FDA, the Corporation now expects to meet important corporate milestone in FY-23 with Phase I/II trial activities now picking up. The Corporation is also assessing various scenarios for addressing the maturity of the remaining \$0.8 million convertible notes due in Q4-23.

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 \$3.2 million April 2022 PIPE financing. ORT has adequate financial resources to start implementing its Ortho-R rotator cuff tear repair clinical program in FY-23. (See "Overview of the Business" and "Going concern").

## **Future financing**

As of April 30, 2022, ORTI had 33.8 million warrants outstanding with an average exercise price of \$0.42. 32.7 million warrants are subject to an acceleration clause. 16 million warrants issued as part of the April 2022 PIPE can be accelerated ff the average VWAP of the Corporation's shares over any ten (10) consecutive trading days (the "Trading Period") is greater or equal to \$0.50 (the "Accelerator price"), 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. Same applies for 16.7 million warrants with an accelerator price of \$1.00 but will require a 20-day trading period.

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 Q1-23 and for which the acceleration clause applied, the maximum influx of cash to the Corporation would have been approximately \$13.9 million. Assuming all warrants are exercised prior to their maturity a total of \$14.2 million could be raised.





(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. However, the Corporation has recently announced receiving a \$0.5 million grant specific to the development of Ortho-M. This grant will cover 80% of the costs associated with the initial R&D activities related to this program and should lead to completion of pre-IND activities in FY-24.

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, ORTI 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 August 15, 2022. 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, 2022 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 2022 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.