

ORTHO Regenerative Technologies Inc.

(CN.ORTH - CSE)

Meniscus Plan In Place

Based on our DCF model and a 15% discount rate, Ortho is valued at approximately \$1.80 per share. Our model applies a 12% probability of ultimate approval and commercialization for the RESTORE platform in the rotator cuff and meniscus programs. The model includes contributions from US and global sources.

Current Price (12/22/2020) \$0.60
Valuation (\$CAD) \$1.80

OUTLOOK

Ortho is developing its RESTORE platform that enables biologics and other regenerative medicines to be delivered to surgery sites in order to enhance healing and guide the regeneration of new tissue. The platform relies on a proprietary chitosan-based biopolymer matrix which is combined with platelet rich plasma (PRP) to improve the success rate of rotator cuff tear (RCT) and meniscus tear (MT) repair surgery. The company's sole product is Ortho-R.

Ortho's RCT program has completed its preclinical stage and is expected to enter clinical trials by early 2021 with IND efforts underway. The MT program is anticipated to enter the clinic in 2022. There is a substantial unmet need in both indications due to the high surgical failure rates that may be successfully improved with Ortho's products.

Approval for Ortho-R in RCT is expected in 2025 followed by MT in 2026. Partner-led commercialization is targeted for RCT in the US in 2025, followed by Canada & the EU the following year. Commercialization of MT is modeled one year behind the RCT program.

RESTORE may also address cartilage repair and improve the outcome of other musculoskeletal soft tissue repair conditions.

SUMMARY DATA

52-Week High 0.99
52-Week Low 0.19
One-Year Return (%) 155
Beta 1.34
Average Daily Volume (sh) 76,275

Shares Outstanding (mil) 33.1
Market Capitalization (\$mil) 19.9
Short Interest Ratio (days) 0.15
Institutional Ownership (%) 0.0
Insider Ownership (%) 30.5

Annual Cash Dividend \$0.00
Dividend Yield (%) 0.00

5-Yr. Historical Growth Rates
Sales (%) N/A
Earnings Per Share (%) N/A
Dividend (%) N/A

P/E using TTM EPS N/A
P/E using 2021 Estimate N/A
P/E using 2022 Estimate N/A

Zacks Rank N/A

Risk Level Above Average
Type of Stock Small-Growth
Industry Med-Biomed/Gene

ZACKS ESTIMATES

Revenue

(In millions of CAD)

	Q1	Q2	Q3	Q4	Year
	(Apr)	(Jul)	(Oct)	(Jan)	(Jan)
2020	\$0.0 A				
2021	\$0.0 A	\$0.0 A	\$0.0 A	\$0.0 E	\$0.0 E
2022					\$0.0 E
2023					\$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2020	-\$0.02 A	-\$0.03 A	-\$0.03 A	-\$0.02 A	-\$0.10 A
2021	-\$0.04 A	-\$0.03 A	-\$0.03 A	-\$0.02 E	-\$0.12 E
2022					-\$0.13 E
2023					-\$0.11 E

WHAT'S NEW

Third Quarter Fiscal Year 2021 Operational and Financial Results

Ortho Regenerative Technologies Inc. (CSE: ORTH.CN / OTC: ORTIF) **reported** third quarter fiscal year 2021 financial and operational results and **submitted** its SEDAR filings on December 18, 2020. During 3Q:21, extending from August 1 to October 31, 2020, Ortho raised a total of \$2.6 million¹ through two non-brokered private placements, Ortho-R was designated a Drug/Biologic combination product by the FDA, Ortho-R continued progress toward US Phase I/II trials and began trading on US OTCQB under the ticker ORTIF. Following the quarter, Ortho completed another non-brokered private placement for gross proceeds of \$3.0 million. This report is the first update since our November 23rd **initiation**. Ortho is on its way to begin clinical studies and believes that the investigational new drug (IND) application for Ortho-R in rotator cuff repair will take place in the first part of January 2021 with first patient enrollment to begin following clearance.

In the financial sphere, no revenues were recognized in 3Q:21 and operating expense fell 11% to \$634,000 relative to 3Q:20. For the three months ended October 31, 2020, compared to the three months ended October 31, 2019:²

- Net expenses for R&D were \$191,000, down 55% from \$421,000 (\$347,000 with adjustment for tax credit), primarily on timing of non-recurrent expenses related to the pivotal Ortho-R animal study completed in 1Q:21, including \$14,000 in tax credits absent in Q3:20;
- G&A expenses were \$342,000, up 35% from \$254,000, on an increase in investor relations spending, partially offset by a decrease in other consulting fees;
- Share-based compensation was \$101,000, up 181% from \$36,000 as options were issued to staff, consultants and board members including non-recurrent grant to scientific advisory board as well as contractual vesting for management on outstanding options;
- Financial expenses were \$179,000, compared with \$49,000. The change was primarily driven by an increase in the company's interest-bearing financing in FY21 as a result of \$3.2 million in CDU³ financings;
- The above resulted in a net loss of (\$813,000) vs (\$760,000) in the prior period.

As of October 31, 2020, cash was \$809,000 and cash burn was (\$1.5 million) for the quarter, just over twice the (\$0.7) million recognized in the prior year period. Financing cash flows were \$2.3 million reflecting proceeds from issuance of units.

During the third quarter, Ortho-R was **designated** a Drug/Biologic by the FDA, the company's shares **began** trading on OTCQB market in the US under the ticker ORTIF, Mukesh Ahuja was **appointed** as VP Clinical and Medical Affairs, and Ortho closed two consecutive non-brokered private placements with combined gross proceeds of \$2.6 million. Following the end of the reporting period, Ortho **completed** another non-brokered private placement for gross proceeds of \$3.0 million.

Candidates

Ortho's lead candidate, Ortho-R is preparing to enter the clinic. The product is built on the company's RESTORE platform and is applied to rotator cuff tear (RCT) injury repair. Ortho-R recently completed its animal pivotal trials which generated positive results in March 2020 and follow-on histology results in July, providing the necessary data to consult with the FDA and develop an investigational new drug (IND) application. We anticipate that the IND will be submitted in the first part of January which, if no questions are raised, will allow Ortho to begin clinical trials in 1Q:21.

Ortho has provided guidance for its meniscus program which is expected to start in early 2021, funding permitting.⁴ Contract research organization selection and protocol development will be followed by a six-month study in 36 sheep. Interim data will be provided at the three month mark and study results are targeted to be available by 1H:22. Further updates will be provided when available.

¹ All reported currency in Canadian Dollars unless otherwise stated.

² Prior year income statement items have been changed from originally reported numbers due to alternate recognition of an investment tax credit of \$74.

³ Convertible Debenture Units

⁴ See Exhibit I below for timeline detail on the meniscus program.

Non-brokered Private Placements

In **August** and **September** 2020, Ortho completed two consecutive placements under the same terms. The placements were non-brokered and private, together totaling \$2.6 million. The first placement issued 7,733,812 units at a purchase price of \$0.32 per unit for gross proceeds of \$2,474,820. Each unit consisted of one class A share and one share purchase warrant. Each warrant is exercisable into one share at \$0.50 for 36 months from closing. Included were further stipulations pertaining to VWAP over any consecutive 20 trading days greater or equal to \$1.00 giving the company the option to give notice to warrant holders, at any time after February 5, 2021, of 30 days until unexercised warrant expiry. The first issue was supported by \$353,000 from internal funding sources. The subsequent placement was again non-brokered and private, conducted on the same terms as the former, issuing 430,000 units at \$0.32 per unit yielding proceeds of \$137,600, bringing the total of the two issues to \$2.6 million.

On December 3, 2020, Ortho **announced** that it had completed yet another non-brokered private placement of secured non-convertible debenture units for gross proceeds of \$3.0 million. Insider contributions totaled \$350,000. Ortho issued 3,000 secured non-convertible debenture units at \$1,000 per unit for gross proceeds of \$3.0 million. Each debenture unit consists of one three-year 10% secured non-convertible debenture in principal amount of \$1,000 and 500 class A share purchase warrants, exercisable at \$0.75 at any time up to 36 months following closing. Proceeds from the raise will be used toward Ortho-R IND submission, clinical site qualification and training, Ethical Review Boards approval and administration, patient enrollment and general corporate administration.

Investment Thesis

Key reasons to own Ortho Regenerative Technologies shares:

- **Safe biopolymer combination product with favorable properties**
 - **Rapid coagulation**
 - **Avoids shrinkage**
 - **Adheres to soft tissues**
 - **Increases biologics residency time to augment and guide regeneration of new tissue**
- **Demonstrated decreased tendon gap and improved bone structure in large animal RCT model**
- **No treatment-specific safety issues**
- **Sufficient capital raised to start phase I/II study in rotator cuff indication**
- **Unmet need in large markets with poor surgery success rates**
 - **About half of RCT surgeries fail**
 - **20% - 40% MT surgeries fail**
- **Biologic product uses autologous PRP which can be sourced quickly and easily**

Exhibit I – Ortho RTI Corporate and Clinical Milestones⁵

Past and Projected Milestones	Calendar Year 2019-2022	Calendar Quarters/Years												
		2019	Q1-20	Q2-20	Q3-20	Q4-20	Q1-21	Q2-21	Q3-21	Q4-21	H1-22	H2-22		
Corporate / Strategic	MTA collaboration - Initial Phase	Initial Phase	☑											
	MTA collaboration - Step 2	On-Hold (Covid-19)		○										
	Licensing Agreement - Ingenew Pharma			☑										
Finance	US OTC-QB Listing				→	■								
	Debenture Financings		☑	☑										
	Private Placement - Unit Offering (\$2.6M)				☑									
	Non-Convertible Debenture Financing (\$3M)					☑								
Clinical Trial Ortho-R Rotator Cuff repair	CMC Manufacturing	Scale-up	→	☑										
		Stability 2yrs - shelf life data	→		☑									
		Stability 3yrs - shelf life data	→											■
		Clinical batch			→		□	■						
	6-month pivotal animal trial	in-life portion	☑											
		results			☑									
	Pre-IND Meeting - FDA		☑											
	US-FDA IND	Filing Pre-RFD		☑										
		Drug/Biologic Designation			☑									
		IND Preparation					☑							
		IND filing					□	■						
		IND approval (30 days post filing)					□	■						
	US Phase I/II Clinical trial	CRO Selection	☑											
		Protocol completion				☑								
		Lead Investigator selection				☑								
		Study sites selection						■						
		Phase I/II trial START					□	→						
		First patient enrolled							■					
		50% enrolment completed								■				
		enrolment completed									■			
	12-mth patient follow up completed										■			
	Study results											■		
Ortho-R Meniscus Program (commitment to start and fund this program may be subject to securing further financing)	6-month Large animal pivotal trial	CRO Selection and Protocol						■						
		in-life portion Start							→					
		3-mth in life data									■			
		in-life portion Ends										■		
	study-results											■		

→ Initiation
 □ previous target last quarter
 ■ Current Target
 ☑ Completed
 ☑ Completed since last MD&A
 ○ On-Hold

Corporate Milestones

- RCT MRI evaluation positive results from pivotal preclinical study – March 2020
- \$1.1 million private placement closed – April 2020
- Licensing agreement with Ingenew Pharmaceuticals – May 2020
- Michael Atkin nominated Chairman of the Board – June 2020
- RCT histology evaluation positive results from pivotal preclinical study – July 2020
- FDA designation and jurisdictional assignment for Ortho-R – August 2020
- \$2.5 million private placement closed – August 2020
- Trading under ticker ORTIF began on the OTCQB – October 2020
- Mukesh Ahuja M.D., appointed VP of Clinical and Medical Affairs - November 2020
- \$3.0 million private placement closed – December 2020

Summary

Ortho RTI has developed a promising product that will enter the clinic shortly. The unmet need in rotator cuff tear and meniscus tear (MT) repair is clear and sizable, which should provide substantial demand following approval. With a recent string of fundraising successes and progress with the FDA, we anticipate a relatively rapid development process as Ortho advances from pilot to pivotal trials, regulatory authority approval and first sales by 2025 in the United States. Our valuation work assumes addressable markets in RCT and MT in the US, EU and Canada with an anticipated 12% probability of success due to Ortho-R's preclinical status. We maintain our valuation of \$1.80 per share.

⁵ ORTH 3Q:21 Financial Report

PROJECTED FINANCIALS

Ortho Regenerative Technologies Inc. - Income Statement

Ortho Regen Tech Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 E	2021 E	2022 E	2023 E
Total Revenues (\$CAD)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Research & Development	\$950	\$365	\$195	\$191	\$400	\$1,151	\$2,611	\$4,500
General & Administrative	\$995	\$507	\$186	\$342	\$250	\$1,285	\$1,719	\$1,755
Share Based Compensation	\$165	\$20	\$49	\$101	\$45	\$215	\$190	\$200
Income from operations	(\$2,110)	(\$892)	(\$430)	(\$634)	(\$695)	(\$2,651)	(\$4,520)	(\$6,455)
Financing Expense	\$306	\$168	\$201	\$179	\$90	\$638	\$360	\$0
Pre-Tax Income	(\$2,416)	(\$1,060)	(\$631)	(\$813)	(\$785)	(\$3,289)	(\$4,880)	(\$6,455)
Provision for Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>	<i>0.0%</i>
Net Income	(\$2,416)	(\$1,060)	(\$631)	(\$813)	(\$785)	(\$3,289)	(\$4,880)	(\$6,455)
Reported EPS	(\$0.10)	(\$0.04)	(\$0.03)	(\$0.03)	(\$0.02)	(\$0.12)	(\$0.13)	(\$0.11)
Basic Shares Outstanding	24,752	24,752	24,779	31,025	33,200	28,439	38,841	56,675

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

Ortho Regenerative Technologies Inc. – Share Price Chart⁶



⁶ Source: barchart.com

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