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ORTHO Regenerative Technologies Inc.

(CN.ORTH - CSE)

Clinical Hold Delays 4 – 6 Weeks

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 (6/3/2021)	$0.44
Valuation ($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 in 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	**0.30**
One-Year Return (%)	**18.9**
Beta	**1.18**
Average Daily Volume (sh)	**38,194**
Shares Outstanding (mil)	**34.9**
Market Capitalization ($mil)	**15.4**
Short Interest Ratio (days)	**0.06**
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 (Apr)	Q2 (Jul)	Q3 (Oct)	Q4 (Jan)	Year (Jan)
2020	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
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	-$0.04 A	-$0.13 A
2022					-$0.13 E
2023					-$0.13 E

WHAT'S NEW

Fourth Quarter and Fiscal Year 2021 Operational and Financial Results

Ortho Regenerative Technologies Inc. (CSE: ORTH.CN / OTC: ORTIF) submitted its SEDAR filings and reported fiscal year 2021 financial and operational results for the period ended January 31 on May 31 and June 1, 2021 respectively. Since the release of third quarter results, Ortho has manufactured its first clinical batch of biopolymer, filed its investigational new drug application (IND) and selected its CRO and study protocol. Several clinical sites have also been confirmed. On June 4, 2021 Ortho issued a press release announcing that it has received a clinical hold letter from the FDA that is expected to delay the IND review by four to six weeks.

Highlights for the fourth quarter fiscal year 2021 and to-date include:

- Raised funds in a non-brokered CAD$3.0 million private placement;
- Executed global license with Hanuman Pelican, Inc.;
- Engaged Westwicke ICR for investor relations;
- Launched Agoracom Platform;
- Augmented Board of Directors with Patrick O'Donnell;
- Secured DTC eligibility for OTCQB market trading;
- Submitted IND application for Ortho-R; and
- Received Clinical Hold Letter from the U.S. FDA.

As a clinical-stage company, Ortho has not generated revenues during any of the reviewed periods. For the three months ended January 31, 2021, compared to the three months ended January 31, 2020, operational expenses are as follows:[1,2]

- Net expenses for R&D were $390,000, up 177% from $141,000, driven by preparatory activities in anticipation of Ortho-R Phase I/II clinical trial including cGMP manufacturing as well as regulatory work for the IND filing;
- Investment Tax Credit recovery was $62,000 versus $46,000, rising 35% despite a decrease in the recovery rate, as recoverable expenses have increased due to cGMP activities in Quebec;
- G&A expenses were $472,000, up 247% from $136,000, resulting from an increase in IR spending as well as consulting fees paid to management;
- Share-based compensation rose 51% to $112,000 from $74,000 on non-recurring grant to Scientific Advisory Board members as well as options vesting to management;
- Financial expenses were $294,000 vs $125,000, rising 135% as Ortho financed its operations with interest-bearing instruments; and
- The above line items contributed to a net loss of ($1.27) million vs ($476,000), or ($0.04) and ($0.02) per share, respectively.

On January 31, 2021, cash on the balance sheet totaled $2.38 million. Cash burn for FY:21 was ($2.98) million which was offset by $5.05 million of cash from financing. This compares to FY:20 cash burn of ($1.59) million and net financing contributions of $1.37 million.

IND Application for Ortho-R

Submission of Investigational New Drug Application for Ortho-R

On April 6, 2021, Ortho announced that it had submitted an Investigational New Drug (IND) application to the FDA for the initiation of a Phase I/II clinical trial for Ortho-R. Following the submission the FDA had additional questions and requested protocol modifications. In a June 4 press release, Ortho announced that a clinical hold had been

[1] Prior year income statement items have been changed from originally reported numbers due to alternate recognition of an investment tax credit of $74.
[2] Financial statement items are denominated in Canadian Dollars.

placed on the trial pending the collection of additional chemistry, manufacturing and control (CMC) related data and characterization of the chitosan product. Management estimates that collecting and submitting the data will take from four to six weeks. Following the delivery of the requested information and assuming the FDA has no further questions, clearance of the IND is anticipated approximately 30 days later, suggesting an August start to the trial.

Phase I/II trial

Following clearance of the IND, Ortho will begin its in-human trial. The company has confirmed seven sites and is in negotiations with about ten others. The target number of sites is from 8 to 12 (up from the previous 6 to 10 sites) with each adding 2 to 6 subjects per month, suggesting completion of the targeted 78 patient enrollment in and completion of trial within six to eight months. Under advisement from the FDA, the first three patients will be treated in the same center with 48 hour separation to ensure there are no safety issues. The trial will be a prospective, randomized, controlled and blinded study to evaluate safety and efficacy of Ortho-R. The treatment will be administered with standard-of-care surgery and will be compared against surgery alone.

Exhibit I – ORTHO-R Phase I/II Rotator Cuff Tear US Clinical Trial[3]

ORTHO-R + Standard of Care Surgery vs. Standard of Care Surgery alone

Prospective, randomized, controlled and blinded Phase I/II study

Primary endpoint:

- Safety (unexpected adverse events)

Secondary endpoints:

- Pain (VAS)
- Validated shoulder function score index
- MRI healing/structural assessment
- Number of re-tears

Assessments:

Baseline – 6 weeks – 3, – 6, – 12 months

Enrollment:

- 25 patients in control arm and 50 patients in Ortho-R arm (1:2 ratio)
- Standard of care (Suture with anchors) VERSUS Standard of care + Ortho-R (proprietary CHITOSAN + autologous PRP)
- 6-10 clinical sites in the US

Non-brokered Private Placements

Following placements in August and September 2020, Ortho announced on December 3, 2020 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.

Global License with Hanuman Pelican, Inc.

Ortho announced on January 5, 2021 that it had entered into an agreement with Hanuman Pelican, Inc. providing Ortho with global rights (excluding Japan) to commercialize Hanuman's Buoy Suspension Fractional System as a

[3] Source: April 2021 Ortho RTI Corporate Presentation.

part of a turnkey offering for Ortho-R. The deal also provides Ortho rights to use the buoy system for all US clinical sites participating in Ortho-R Phase I/II trials for rotator cuff tear (RCT) repair.

The agreement specifically grants Ortho license to use, manufacture, sublicense and sell Hanuman's buoy system in fields including tendons, ligaments, meniscus, cartilage and wound healing.[4] Hanuman has also agreed to supply its system as the exclusive platelet-concentration system to each of the sites participating in Ortho's clinical trial. As a part of the agreement, Ortho will pay royalties on net sales of the Ortho-R package attributable to the Hanuman system. Additional detail regarding the Hanuman Buoy System is available in our prior article.

Recent Developments

Westwicke IR
On February 4, 2021, Ortho announced that it had retained Westwicke, an ICR company, for the purposes of US Investor Relations. Westwicke Partners is focused on the healthcare sector and provides strategic investor relations and independent capital markets advice.

Investor Outreach
Ortho launched its 12-month online investor outreach campaign through the Agoracom platform, announced in a February 10th press release. The purpose of the campaign is to broaden Ortho's shareholder base, and also to attract new investment as well as engaging current shareholders. Agoracom will provide Ortho digital exposure with its over 600 million page views in 2019, serving over 350 public companies. Ortho's landing page on the Agoracom platform can be found here.

DTC Eligibility for OTCQB Trading
Ortho common shares are now eligible for electronic clearing and settlement through the Depository Trust Company (DTC) in the US, an important step in facilitating the trade of Ortho equity for US based investors and firms. Clearing and settlement through the DTC is expected to allow for faster execution and improved liquidity for company shares. Eligibility was announced March 31, 2021.

Patrick O'Donnell Appointed To Board, Buschmann and Hoemann Step Down

On February 24, 2021, Ortho announced that Patrick O'Donnell was appointed to its Board, effective immediately. O'Donnell brings company-building experience as well as development and management of strategic partnerships. In addition, O'Donnell has expertise in fund raising as well as executing commercial, clinical, regulatory and reimbursement strategies.

Patrick O'Donnell is President and CEO of HD LifeSciences and has over 25 years of experience leading companies in various stages, specializing in the medical device, orthobiologics and biomaterial industries targeting orthopedic, spine, neurosurgery and sports medicine markets. Prior to serving HD LifeSciences, O'Donnell was Executive Vice President and General Manager of Commercial Operations at Bonesupport A.B., co-founder and CEO of Proteothera, Inc., President and CEO of Histogenics Corporation/Prochon Biotech, Inc., Director of Global Marketing for Confluent Surgical, Inc. and held positions of escalating responsibility in sales and marketing at Johnson & Johnson, DePuy Spine. He received his bachelor's from the University of Wisconsin-Madison.

Coincident with O'Donnell's appointment, it was announced that Board members Michael Buschmann and Caroline Hoemann would retire from Ortho's Board, effective February 22, 2021. Both have served Ortho for over five years as founders, inventors, and as members of both the company's Board and Scientific Advisory Board (SAB). They will continue to serve on Ortho's SAB, and Buschmann will continue in his position as Chief Scientific Officer.

Candidates

As of Ortho's latest update, 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. An IND has been filed for Ortho-R and is awaiting approval by the FDA. Pending approval, the Phase I/II trial for Ortho-R is expected to initiate in late summer 2021, enrollment completion in the first half 2022, and study results as early as first half 2023.

[4] Wound healing field is non-exclusive

Exhibit II - Ortho Product Pipeline[5]

Ortho has provided guidance for its meniscus program which is expected to start in early 2021, funding permitting.[6] 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.

Exhibit III – Ortho RTI Corporate and Clinical Milestones[7]

Past and Projected Milestones	Calendar Year 2019-2023		Calendar Quarters/Years											
			2019	Q1-20	Q2-20	Q3-20	Q4-20	Q1-21	Q2-21	Q3-21	Q4-21	H1-22	H2-22	H1-23
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)						☑							
Ortho-R Rotator Cuff repair Progam	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 Preperation					☑							
		IND filing							☑					
		IND approval							■					
	US Phase I/II Clinical trial	CRO Selection	☑											
		Protocol completion				☑								
		Lead Investigator selection				☑								
		Study sites selection						➔	■					
		Clinical sites qualification & training							■					
		Phase I/II trial START							➔					
		First patient enrolled								■				
		50% enrolment completed									■			
		enrolment completed										■		
		12-mth patient follow up completed												■
		Study results												■
Ortho-M Meniscus Program	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										■		

new
on track

➔ Initiation
■ Current Target

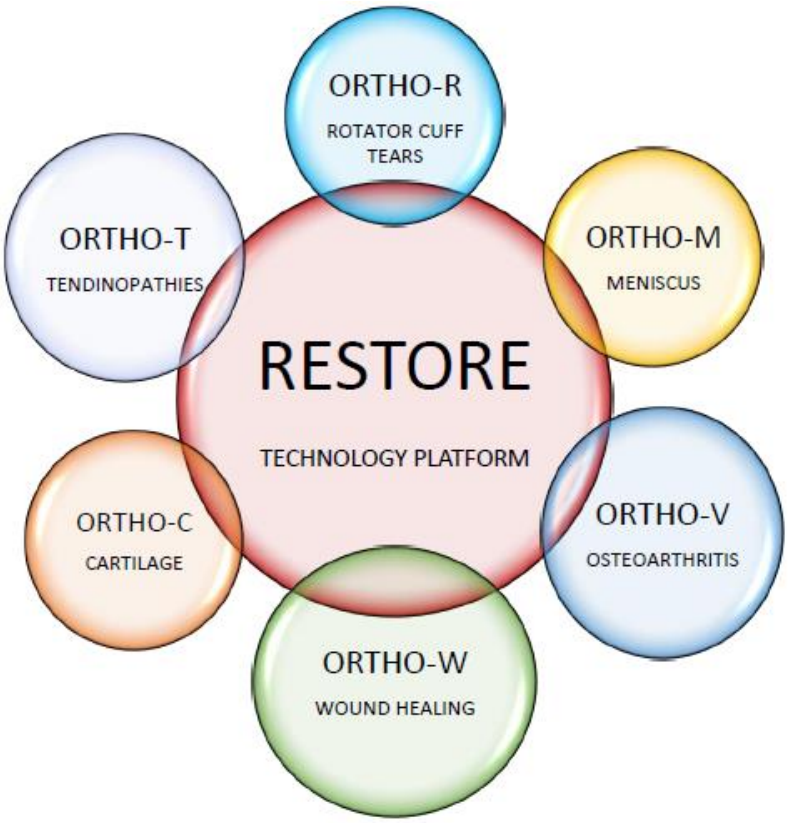
☑ Completed
☑ Completed since last MD&A
⊙ On-Hold

[5] Source: April 2021 Ortho RTI Corporate Presentation
[6] See Exhibit I below for timeline detail on the meniscus program.
[7] Source: April 2021 Ortho RTI Corporate Presentation

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
- IND Filing - April 2021
- Launch of Phase I trial – August 2021
- Phase I/II Clinical Results – 1H:23

Exhibit IV – Corporate Strategic Vision[8]



Summary

Ortho RTI has developed a promising product that is expected to begin enrolling patients by the end of the summer. 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. Despite a modest delay in the start of the Phase I/II trial, we maintain our valuation of $1.80 per share.

[8] Source: April 2021 Ortho RTI Corporate Presentation

PROJECTED FINANCIALS

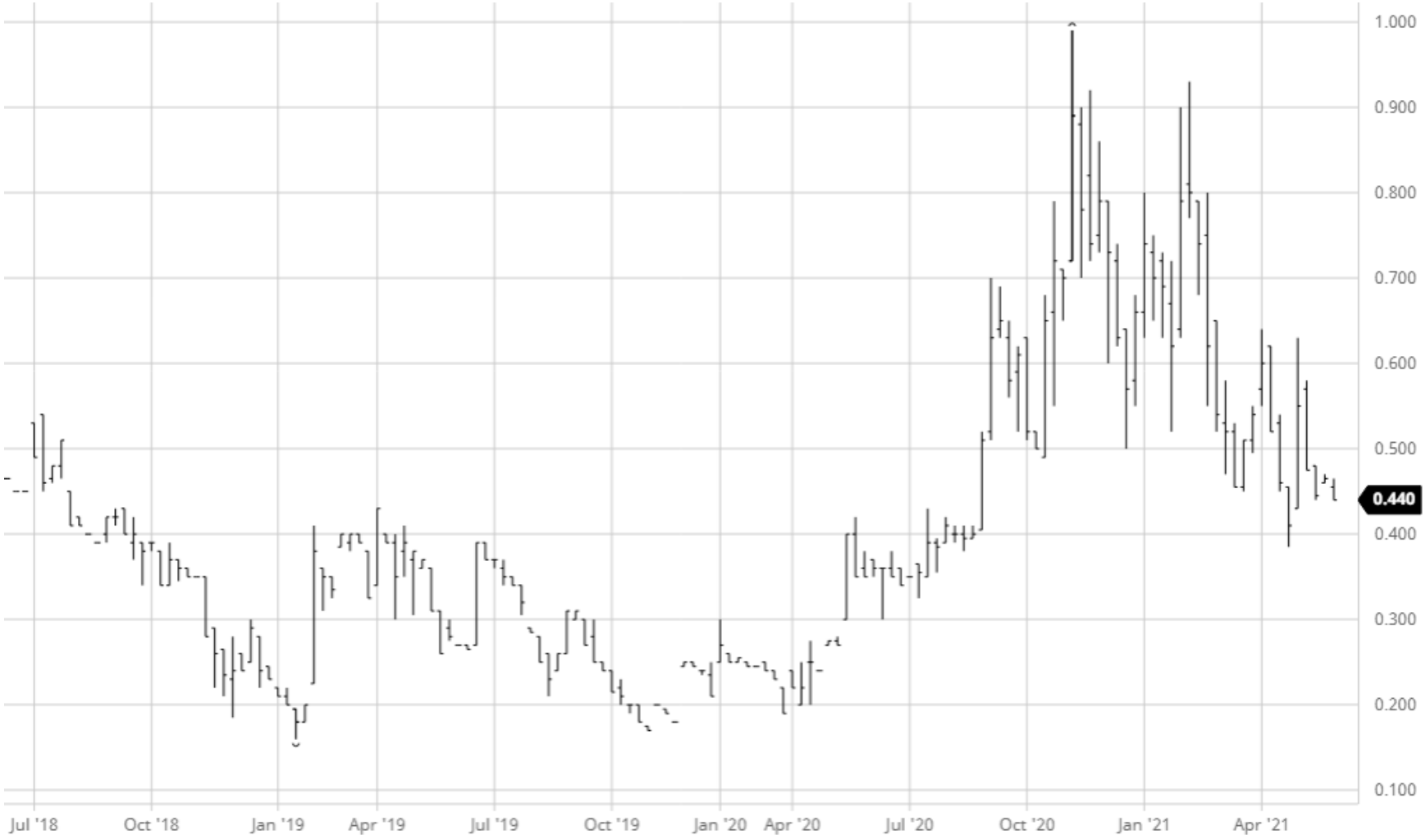
Ortho Regenerative Technologies Inc. - Income Statement

Ortho Regen Tech Inc.	2020 A	Q1 A	Q2 A	Q3 A	Q4 A	2021 A	2022 E	2023 E
Total Revenues ($CAD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$950	$365	$195	$191	$390	$1,141	$2,127	$4,500
General & Administrative	$995	$507	$186	$342	$472	$1,507	$1,669	$1,755
Share Based Compensation	$165	$20	$49	$101	$112	$282	$185	$200
Income from operations	($2,110)	($892)	($430)	($634)	($974)	($2,930)	($3,981)	($6,455)
Financing Expense	$306	$168	$201	$179	$294	$842	$1,100	$1,100
Pre-Tax Income	($2,416)	($1,060)	($631)	($813)	($1,268)	($3,772)	($5,081)	($7,555)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($2,416)**	**($1,060)**	**($631)**	**($813)**	**($1,268)**	**($3,772)**	**($5,081)**	**($7,555)**
Reported EPS	**($0.10)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.13)**	**($0.13)**	**($0.13)**
Basic Shares Outstanding	24,752	24,752	24,779	31,025	34,034	28,749	37,841	56,675

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

HISTORICAL STOCK PRICE

Ortho Regenerative Technologies Inc. – Share Price Chart[9]



[9] Source: barchart.com

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