Zacks Small-Cap Research

Sponsored – Impartial – Comprehensive

July 7, 2021

John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

ORTHO Regenerative Technologies Inc.

(CN.ORTH - CSE)

First Quarter Update

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 (7/6/2021)	$0.33
Valuation ($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 development 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	**0.32**
One-Year Return (%)	**-2.94**
Beta	**1.13**
Average Daily Volume (sh)	**30,124**
Shares Outstanding (mil)	**34.9**
Market Capitalization ($mil)	**11.5**
Short Interest Ratio (days)	**0.02**
Institutional Ownership (%)	**0.00**
Insider Ownership (%)	**22.7**
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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 E	$0.0 E	$0.0 E	$0.0 E
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2021	-$0.04 A	-$0.03 A	-$0.03 A	-$0.04 A	-$0.13 A
2022	-$0.04 A	-$0.03 E	-$0.03 E	-$0.04 E	-$0.14 E
2023					-$0.13 E
2024					-$0.12 E

WHAT'S NEW

First Quarter Fiscal Year 2022 Operational and Financial Results

Ortho Regenerative Technologies Inc. (CSE: ORTH.CN / OTC: ORTIF) filed its quarterly SEDAR documents and reported first quarter fiscal year 2022 financial and operational results for the period ended April 30 on June 29, 2021. Since the beginning of the year, 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 announced that it has received a clinical hold letter from the FDA that is expected to delay the IND review by four to six weeks. We anticipate that questions will be answered and returned to the agency in line with this original timeline.

Highlights for the first quarter fiscal year 2022 and to-date include:

- Engaged Westwicke ICR for investor relations;
- Launched Agoracom Platform;
- Appointed multiple members to Board of Directors;
- Secured DTC eligibility for OTCQB market trading;
- Submitted IND application for Ortho-R; and
- Received Clinical Hold Letter from the U.S. FDA.

No revenues were reported for the first quarter. For the three months ended April 30, 2021, compared to the three months ended April 30, 2020, operational expenses are as follows:[1]

- Net expenses for research and development were $424,000, up 16% from $365,000, driven by activity related to the long-term service contract with Polytechnique, completion of current good manufacturing practices (cGMP) batches of Ortho-R and work related to the IND application with the FDA. Expenses were offset by investment tax credits and grant funding;
- G&A expenses were $416,000, down 18% from $136,000 due to the absence of a non-recurrent management fee incurred in the prior year from an increase in IR spending as well as consulting fees paid to management;
- Share-based compensation rose 215% to $63,000 from $20,000 on non-recurring grant to new board members and contractual vesting for management team members;
- Financial expenses were $338,000 vs $168,000, rising 101% reflecting the new $3 million non-convertible debenture units, existing convertible debenture units and higher interest expense offset by the pay down of investment tax credit loans in the prior quarter; and
- The above line items contributed to a net loss of ($1.24) million vs ($1.06) million, or ($0.04) in each period, with the apparent incongruity between net loss and net loss per share attributable to difference in share count.

On April 30, 2021, cash on the balance sheet totaled $1.61 million. Cash burn for FY:21 was ($852,000) which was offset by $135,000 million of cash from financing. This compares to prior year first quarter cash burn of ($460,000) and net financing contributions of $212,000.

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 IND application to the FDA for the initiation of a Phase I/II clinical trial for Ortho-R. Following the submission, the FDA raised additional questions and requested protocol modifications. In a June 4 press release, Ortho announced that a clinical hold had been placed on the trial pending the collection of additional chemistry, manufacturing and control (CMC) related data and characterization of the chitosan product. Management initially estimated that collecting and submitting the data will take from four to six weeks and confirmed this timeline in a recent call. Following the delivery of the requested information and

[1] Financial statement items are denominated in Canadian Dollars.

assuming the FDA is satisfied, 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 site adding 2 to 6 subjects per month, suggesting completion of the targeted 78 patient enrollment in and completion of the trial within six to eight months. Under guidance 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[2]

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

Recent Developments

Westwicke IR
On February 4, 2021, Ortho announced that it had retained Westwicke to advance investor relations efforts in the United States. 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.

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

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.

Changes to the Board of Directors

The appointment of Howard Walthall and Tim Cunningham to the board of directors was announced in a June 2021 press release. Their experience and skill are expected to help Ortho build into a stronger orthobiologics company on both the operational and financial fronts.

Mr. Walthall's background includes work in cellular biologics, tissue engineering, medical devices and allografts. He has an extensive background in regenerative medicine, orthopedics and advanced wound care. Howard has overseen multiple highly successful product development projects and new product launches. He is currently the President, Founder and CEO of Lumiheal Therapeutics, a company developing and commercializing a patented technology that uses fluorescent light energy to heal chronic and acute wounds, burns and surgical incisions. Previously, Mr. Walthall was the Executive Vice President Strategy and Market Development for Organogenesis where he led sales, marketing and R&D for the Surgical and Sports Medicine (SSM) product lines. He also led the overall Strategy and Business Development functions for the Company and oversaw the International business unit. Howard was the President and Chief Executive Officer of NuTech Medical where he helped build an advanced orthobiologics and wound care business leading to a successful exit via acquisition by Organogenesis. Howard holds a Bachelor of Science in Engineering Biomedical and Mechanical Engineering (B.S.E.) from Duke University, and a Juris Doctor from Samford University Cumberland School of Law.

Mr. Cunningham brings over 30 years of extensive finance and operations leadership in the biotechnology and software industries to his work with his public and private Danforth clients, as a CFO with a demonstrated record of success in building startup enterprises into industry leaders and scaling larger entities globally. His expertise includes financial & strategic planning, P&L management & execution, acquisitions & divestitures, raising equity and debt and post-merger integration. Tim is a trusted advisor and subject matter expert in strategic planning and creative, scalable, business design, and has a proven track record of driving growth leading to either a successful exit via sale or IPO. Tim has raised more than $500M in private equity, public equity and debt in his career. Tim started his career in public accounting with KPMG in NYC and later with PWC in Boston. Prior to joining Danforth, Tim served as CFO at Organogenesis where he took the company public in 2018, raising $144M in equity and $100M in debt over his tenure. Tim holds an MBA from Boston University, a BS in Accounting from Boston College and is a CPA in New York & Florida.

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

Ortho's lead candidate, Ortho-R, is undergoing the final review before IND clearance and entering the clinic. The product is built on the company's RESTORE platform and is applied to rotator cuff tear (RCT) injury repair. Ortho-R completed its animal pivotal trials and follow-on histology results, providing the necessary data to submit an IND application. An IND has been filed for Ortho-R and the company is pursuing FDA 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.

Exhibit II - Ortho Product Pipeline[3]

Ortho has provided guidance for its meniscus program which is expected to start in 2021, funding permitting.[4] Contract research organization selection and protocol development efforts which are underway 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[5]

Rotator Cuff Tears	Q1 2019	Q2 2019	Q3 2019	Q4 2019	Q1 2020	Q2-Q3-Q4 2020	Q1 – Q2 2021	Q4 2021	Q4 2022	H2 2022 Q1-2023	2023	2024
Pre-Clinical Sheep	Pivotal Trial start	Pivotal Trial completion	Pivotal Trial Data analysis.	Pivotal Trial Data analysis.	Pivotal Trial MRI& Safety report	Sheep Pivotal Trial final Report						
CMC (Manufacturing CMO)	API /FP Engineering batch Process Verification	Validation of Analytical Methods	FP Stability study(6 months)		FP Completion of Stability study	API completion of Stability study (6 months)	CGMP clinical batch		Pivotal study clinical batch			
Regulatory	Pre-IND meeting FDA	Pre-IND meeting FDA Q&A		Pre-CTA Consultation Meeting Health Canada	Pre-RFD Application filling FDA	FDA Designation	IND submission & Approval	FDA Pre-Phase III Clinical Study meeting	FDA approval for Phase III Clinical Study			Biologics License Application (BLA) filling FDA
US Phase I/II Clinical Trial			CRO selection MCRA			Clinical Sites qualifications & selection	Clinical sites Training & Start enrolling	Clinical Trial End enrolling	Clinical Trial end follow-up	Clinical Trial Data Analysis & Results		
US and Canada/EU Phase III Clinical Trials									Clinical Trial Start enrolling	Clinical Trial End enrolling	Clinical trial end follow-up	Human P III Clinical Trial Results
Strategic co-development / Licensing						Therapeutics co-development agreement	Clinical Trial Co-development agreement				Licensing Agreement	

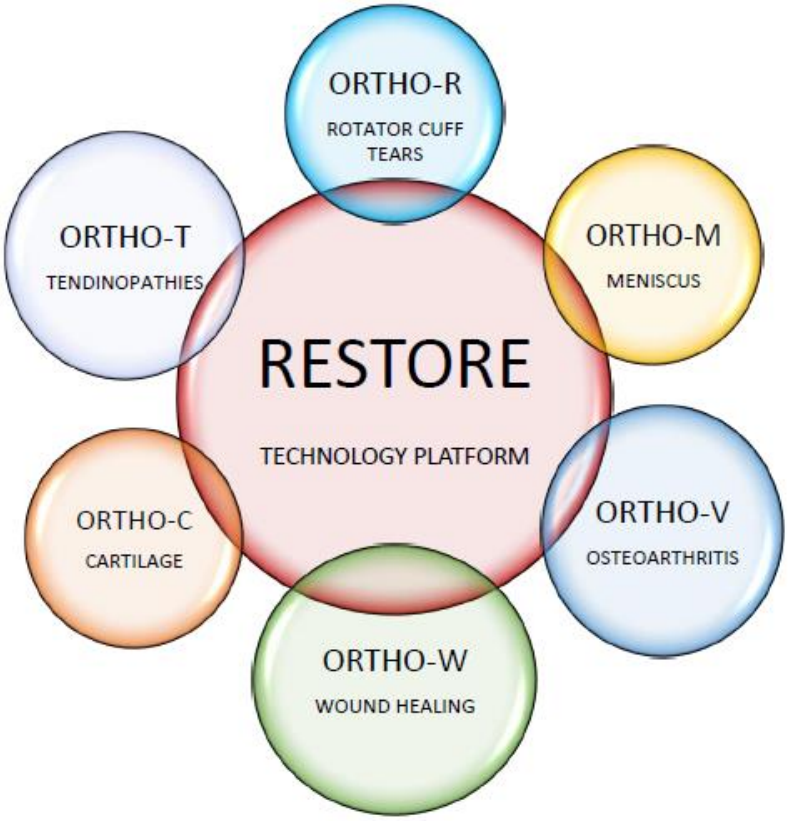
HIGH VALUE INFLECTION POINTS

Corporate Milestones

- IND Filing - April 2021
- Clinical Hold Letter – June 2021
- Preparation and protocol development for meniscus animal studies – mid 2021
- Launch of meniscus animal studies – Fall 2021
- Launch of Phase I trial – August 2021
- Patient enrollment - October 2021
- Phase I/II Clinical Results – 1H:23

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

Exhibit IV – Corporate Strategic Vision[6]



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. We maintain our valuation of $1.80 per share.

[6] Source: April 2021 Ortho RTI Corporate Presentation

PROJECTED FINANCIALS

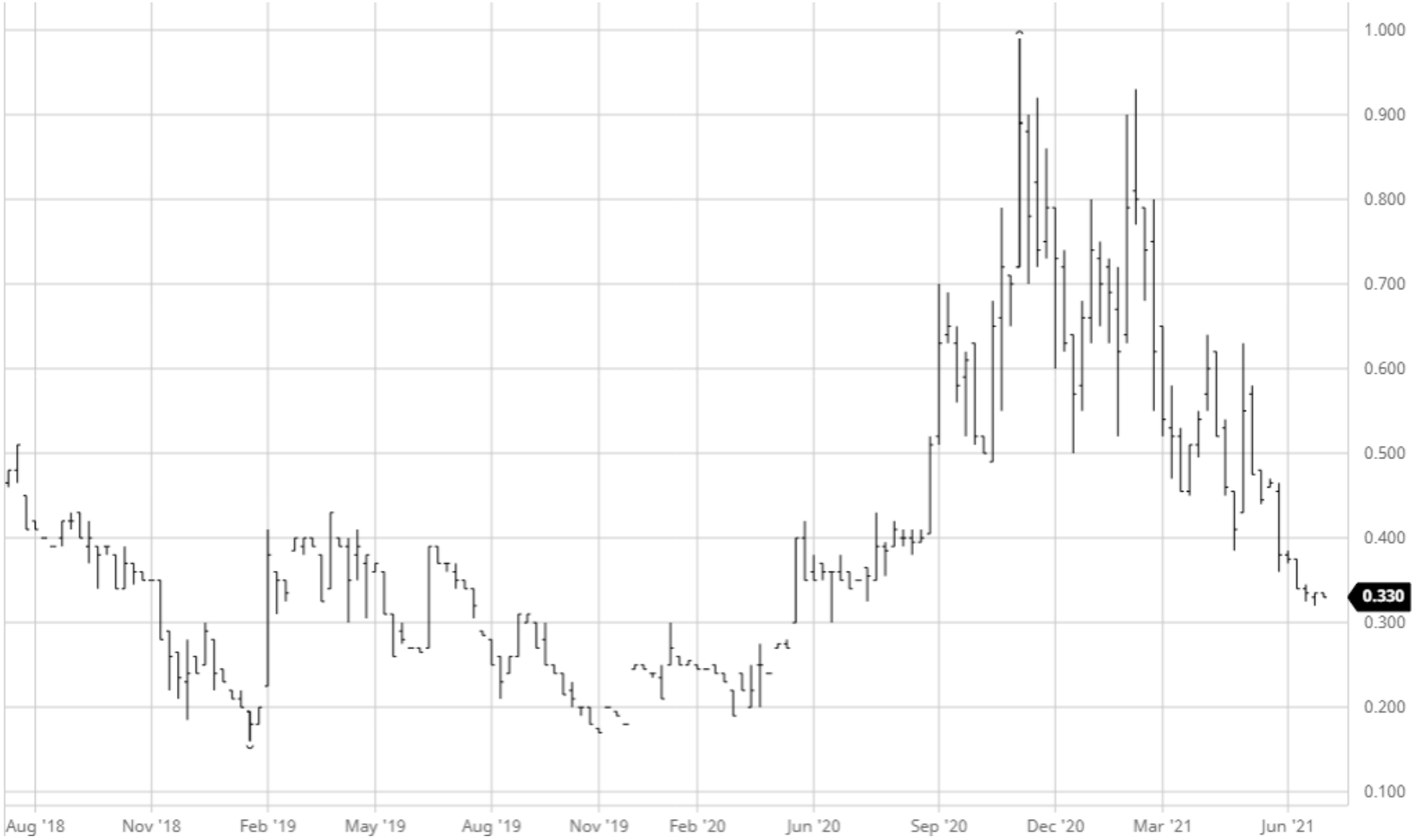
Ortho Regenerative Technologies Inc. - Income Statement

Ortho Regen Tech Inc.	2021 A	Q1 A	Q2 E	Q3 E	Q4 E	2022 E	2023 E	2024 E
Total Revenues ($CAD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$1,141	$424	$348	$649	$782	$2,203	$4,500	$5,500
General & Administrative	$1,507	$416	$400	$410	$459	$1,685	$1,755	$1,854
Share Based Compensation	$282	$63	$45	$45	$50	$203	$200	$210
Income from operations	($2,930)	($903)	($793)	($1,104)	($1,291)	($4,091)	($6,455)	($7,564)
Financing Expense	$842	$338	$275	$275	$275	$1,163	$1,100	$0
Pre-Tax Income	($3,772)	($1,241)	($1,068)	($1,379)	($1,566)	($5,254)	($7,555)	($7,564)
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	**($3,772)**	**($1,241)**	**($1,068)**	**($1,379)**	**($1,566)**	**($5,254)**	**($7,555)**	**($7,564)**
Reported EPS	**($0.13)**	**($0.04)**	**($0.03)**	**($0.03)**	**($0.04)**	**($0.14)**	**($0.13)**	**($0.12)**
Basic Shares Outstanding	28,749	34,873	36,425	39,740	40,800	37,959	56,675	65,200

Source: Company Filing // Zacks Investment R

HISTORICAL STOCK PRICE

Ortho Regenerative Technologies Inc. – Share Price Chart[7]



[7] Source: barchart.com

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, John Vandermosten, hereby certify that the views expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.

Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN DISCLAIMER

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada and is not an associated person of any Canadian registered adviser and/or dealer and, therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.