

## **MANAGEMENT'S DISCUSSION AND ANALYSIS FOR THE THREE AND SIX-MONTH PERIODS ENDED JULY 31<sup>st</sup>, 2018**

### ***MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL REPORTING***

This Management's Discussion and Analysis ("MD&A") for Ortho Regenerative Technologies Inc. (the "Corporation" or "Ortho RTI") 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 on September 14th, 2018 and approved by Ortho RTI's Board of Directors on September 18th, 2018 and should be read in conjunction with the unaudited interim condensed financial statements for the three and six-month periods ended July 31st, 2018. Unless otherwise noted, all amounts are presented in Canadian dollars.

Additional information relating to Ortho Regenerative Technologies Inc. can be found on SEDAR at [www.sedar.com](http://www.sedar.com). The Corporation's shares are publicly traded on the Canadian Securities Exchange ("CSE") under the symbol "ORTH." The Corporation has 24,712,424 common shares that are issued and fully paid as of September 18, 2018th, of which 8,631,644 shares are held in escrow.

The information contained in this MD&A may contain some forward-looking statements. Forward-looking information may include, but is not limited to information with respect to our future financial and operating performance, future development activities and adequacy of financial resources. Forward-looking information is based on the reasonable assumptions, estimates, analysis and opinions of management made in light of its experience. Our forward-looking statements are based on the reasonable beliefs, expectations and opinions of management on the date of this management analysis. Although we have attempted to identify important factors that could cause actual results to differ from those contained in forward-looking information, there may be other factors that cause results not to be as anticipated, estimated or intended. Accordingly, readers should not place undue reliance on forward-looking information.

Ortho Regenerative Technologies Inc. is incorporated under the Canada Business Corporations Act. The Company's head office and principal address and registered office is located at 16667 Hymus Blvd., Kirkland, Quebec, Canada.

This MD&A provides an overview of the Corporation's operations, performance and financial results for the three and six-month periods ended July 31st, 2018, and compares the 2018 results to those of the same period in 2017.

### ***OVERVIEW OF THE BUSINESS***

The Corporation is a research and development biotechnology company, specialized in regenerative medical products that are designed to repair and regenerate damaged joint tissues, thereby helping restore function and prevent or delay the onset of osteoarthritis. The attached financial statements reflect operating costs which are mainly based on the funding of three research agreements under which the regenerative medicine products continue to be developed. Development of regenerative medicine products is inherently expensive, and raising sufficient capital to continue research and development is a major focus of the management team.

The Corporation's activities consist of research and development in the area of tissue repair and regeneration for damaged joint tissues. The Corporation does not have any products approved for sale and

consequently has no revenue, nor does it foresee generating any revenue in the near term. All amounts paid to acquire technologies or know-how have been presented as intangible assets in the statement of financial position, and all costs related to ongoing research and development activities have been presented as research and development costs in the statement of loss and comprehensive loss.

Product	Indication	Stage
Ortho-R	Rotator cuff tears	Large animal studies (development)
Ortho-M	Meniscus tears	Large animal studies (development)
Ortho-V	Osteoarthritis pain	Feasibility (research)
Ortho-C	Articular cartilage	Feasibility (research)

Ortho-R and Ortho-M are freeze-dried formulations that contain a biopolymer, a lyoprotectant and a clot activator. These freeze-dried formulations can be solubilized in platelet-rich plasma (“PRP”) to form injectable implants that coagulate after implantation. Extensive in vitro testing has allowed us to identify specific formulations that meet the following criteria: 1) rapid and complete solubilization in PRP, 2) biopolymer-PRP mixtures which have the paste-like handling properties upon solubilization desired by surgeons, 3) biopolymer-PRP mixtures that coagulate rapidly to form solid biopolymer-PRP hybrid implants, 4) biopolymer-PRP implants that are mechanically stable and resist platelet-mediated clot retraction, and 5) dispersion of the biopolymer in the implants that is homogenous for optimal biodegradability. Biopolymer-PRP implants have been tested in vivo using a subcutaneous injection model in rabbits. Biopolymer-PRP implants were resident for several weeks, while PRP-only controls degraded in one day. Biopolymer-PRP implants induced cell recruitment and angiogenesis, both of which were not seen with PRP-only controls. The biopolymer-PRP implants were biodegradable, as the biopolymer was internalized and degraded by host cells. The biopolymer-PRP implants were also biocompatible, as they did not induce any deleterious effects in this model.

Ortho-R for rotator cuff repair was tested in a small animal rabbit model and then in a larger animal sheep model (a pilot study is complete and a pivotal study is in the planning stage). In the rabbit model, bilateral full-thickness tears were created in the supraspinatus (SSP) tendons of the rotator cuff and the tears were immediately repaired with a transosseous suturing technique. On the treated side, Ortho-R was additionally injected at the repair site, into the bone tunnels and into the SSP tendon. In the pilot study at 2 months, the Ortho-R treatment had partly restored the structural organization of a normal SSP enthesis, with a calcified interface between the tendon and the bone. In contrast, the SSP tendon insertion site in the sutured-only shoulder showed abnormal integration, with significant bone overgrowth into the tendon itself. In the pivotal rabbit study, gaps were present between the stump of the tendon and the humeral head surface in the suturing-only group at 2 months. In contrast, there were no gaps in the Ortho-R treated shoulders. In the sheep model, unilateral full-thickness tears were created in the infraspinatus (ISP) tendons of the rotator cuff, and the tears were immediately repaired with suture anchors in a suture bridge configuration. In the treated shoulders, Ortho-R was additionally injected at the bone-ISP tendon interface and on top of the repaired site. Ortho-R improved ISP tendon structural organization and induced remodeling at the bone-ISP tendon interface at 3 months when compared to suture anchors.

The use of Ortho-R in conjunction with suturing techniques produced promising histological findings in small and large animal models, which is expected to translate into superior rotator cuff repair. No adverse events were found in any of the above-mentioned animal studies, which suggests a high level of safety.

Ortho-M was tested in a bilateral meniscus repair model in sheep. Longitudinal tears of the medial meniscus were treated with suturing as per clinical practice, and Ortho-M implants were injected into the tears via induced channels. Ortho-M was found to be partly resident in the tears and in the channels at 1 day, where they induced cell recruitment from the outer vascular portion of the meniscus. At 3 weeks and at 3 months, a highly cellular and integrated repair tissue was observed in some Ortho-M treated tears, while there was no evidence of tissue repair in any of the PRP-only controls. This bilateral model was challenging, since it did not permit the animals to protect their knees from bearing weight post-operatively, and could contain

only a limited amount of Ortho-M. Even with these limitations, Ortho-M showed significant biological activity and potential to improve meniscus repair, while PRP-only controls did not.

As well, the performance of Ortho-M was assessed in combination with a meniscus wrapping technique in a unilateral complex tear model in sheep. Ortho-M implants showed superior regenerative effects over wrapping the meniscus with a collagen membrane at 6 weeks. Using the wrap in conjunction with Ortho-M did not further improve repair, and the additional sutures needed to secure the wrap created significant damage to the meniscus. This suggests that Ortho-M implants by themselves could be effective in overcoming the current limitations of meniscus repair.

Ortho-C is a freeze-dried matrix with ultra-high porosity designed to augment bone marrow stimulation procedures for articular cartilage repair, including microfracture and drilling. At the point-of-care surgical intervention, the surgeon currently has control over the pattern of bone plate channels created, but methods need to be found to control the activity of the blood clot that forms in the subchondral bone. Ortho-C is specifically designed for delivery to bleeding subchondral blood channels, where it interfaces with blood to create bioactive particles that actively promote a more rapid hemostasis and subsequently guide revascularization of the bone marrow channel, subchondral bone plate remodeling, and articular cartilage regeneration. The scaffold contains a biodegradable naturally-derived polymer, a biopolymer, with a high safety profile. After packaging, sterility testing and quality assurance, the surgeon will have the option of shaping the scaffold and inserting it into the bone marrow channels by open arthrotomy for maximum control, or of using a specific delivery device to insert the scaffold under a drained arthroscopy field. Compared to other augmentation devices, Ortho-C treatment has the advantage of adding only minutes to the marrow stimulation procedure.

Ortho-V is a freeze-dried biopolymer formulation tailored for intra-articular injections and viscosupplementation applications. Most viscosupplementation products use hyaluronic acid, but orthopaedic surgeons are also injecting PRP intra-articularly. Ortho-V consists of a freeze-dried biopolymer that will be solubilized in PRP for intra-articular injections. The biopolymer is expected to cross-link endogenous hyaluronic acid present in the joint and provide viscosupplementation, while PRP will provide platelet-derived growth factors and biological activity. A rabbit model of chemically-induced joint degeneration will be used to test intra-articular injections of Ortho-V.

For the first option, a variety of approaches are possible owing to the potential separation of various indications and geographies, ranging from single indications in a single geography to a full acquisition. The Corporation has no specific preference at this point in time. The Corporation is therefore focused on building value for each of its product lines and those potential products that have not yet entered the pipeline. As with any product in the development phase, value will be created by proving: a) the functional efficacy of the product principally through clinical development, and; b) the commercial viability of such a product in specific marketplaces by obtaining regulatory approvals, generating health economic data and developing a manufacturing capability that can ensure appropriate gross and net margins.

The Corporation currently has sufficient expertise to manage the research and development process for each of the products. The value ascribed to each product is expected to increase significantly as it moves through the development phase and will reach the maximum pre-revenue value at the point where it has proven clinical efficacy and has obtained the required regulatory approvals.

In August 2016, the Corporation received its first U.S. patent, for “SOLUBLE PHYSIOLOGICAL BIOPOLYMER FORMULATIONS COMBINED WITH PLATELET-RICH PLASMA (PRP) FOR TISSUE REPAIR.” The patent covers the use of the Corporation’s biopolymer technology with PRP for tissue repair broadly, and is not limited to any of our specific indications such as the rotator cuff or meniscus. The patent will remain in force until November 2030.

In March 2018, the Corporation received a Notice of Allowance from the European Patent Office for European Patent Application Number 10831000.4 entitled, “Novel Formulation of Physiological Chitosan-Inorganic Salt Solution/Blood Mixtures for Tissue Repair.” The patent will remain in force until November 2030.

In May 2018, the Corporation received a Notice of Allowance from the European Patent Office for European Patent Application Number 10831011.1 entitled, “Soluble Physiological Chitosan Formulations Combined with Platelet-Rich Plasma (PRP) for Tissue Repair”. The patent will remain in force until November 2030.

The Corporation continues to extend and defend its intellectual property. Two other patent families covering specific freeze-dried formulations have now entered the national phase in several jurisdictions. In order to use the Corporation’s resources most efficiently, management has limited the jurisdictions in which it will seek protection to the following: the EU (via a European patent), Canada, the USA, Japan and Australia.

The Corporation’s current focus remains on Ortho-R for the surgical treatment of rotator cuff injuries in the shoulder. Additionally, the principal geographic focus remains the U.S., and therefore the U.S. FDA remains the principal regulatory body for our initial indication(s).

In 2016, a teleconference was held between the Center for Biologics Evaluation and Research (“CBER”) and the Corporation (represented by the Corporation’s regulatory consultants, the CEO and Dr. Buschmann). Discussions with the FDA ensued, and it has been determined that Ortho-R will be regulated as a single-entity biologic through CBER. The specific implications of this determination remain to be quantified, but it is possible that an increased investment in chemistry, manufacturing and controls (“CMC”) may be required. This being said, it has been clarified with CBER that the earlier anticipated ISO10993 package of biocompatibility studies will not be required for continued development. In addition, CBER broadly suggested that the proposed preclinical package should be sufficient to begin human clinical trials, and that the draft clinical development plan appears appropriate at this stage.

There are now two major work components that must be completed before any clinical evaluation can take place:

The manufacture of Ortho-R must satisfy Current Good Manufacturing Practice (“CGMP”) regulations so that proper clinical trial supplies can be manufactured for regulated clinical studies. It has always been the Corporation’s intention to undertake an agreement with a suitable contract manufacturing organization (“CMO”), but not to invest in the development of its own facilities. Therefore, a master service agreement has been signed with KABS Laboratories Inc. (“KABS”). KABS has all the necessary facilities for processing our raw material into a final product and providing the required quality control and stability studies. In addition, KABS appears to have all the necessary quality systems required for our purposes. The Corporation has received samples of several batches of the raw material from our preferred supplier. This material will be sufficient to manufacture the final product for early clinical trials.

Second, all preclinical studies must be completed, involving evaluations of both the safety and the efficacy of Ortho-R in a large animal efficacy model. In the fall, we completed the pilot study which we believe has demonstrated the suitability of the preclinical model. A local contract research organization (“CRO”) has been selected to undertake the pivotal preclinical study, and contract negotiations are ongoing, along with the necessary quality audit.

All the activities described above have been planned and are being executed as sufficient financial resources have been secured.

## SELECTED FINANCIAL DATA

The following table sets forth financial information for the Corporation for the periods indicated and should be read in conjunction with the interim condensed financial statements for the three and six-month periods ended July 31st, 2018 and 2017.

	Three months ended		Six months ended		Q2- FY2019 Change	YTD- FY2019 change
	Q2FY2019 July 31, 2018	Q2FY2018 July 31, 2017	YTDFY2019 July 31, 2018	YTDFY2018 July 31, 2017		
	\$	\$	\$	\$	\$	\$
Research and development costs	<b>111,973</b>	86,530	<b>259,816</b>	153,081	(25,443)	(106,735)
General and administrative expenses	<b>333,166</b>	296,315	<b>592,524</b>	462,601	(36,851)	(129,923)
Financial charges	<b>38,661</b>	(10,166)	<b>83,421</b>	13,794	(48,827)	(69,627)
Change in fair value of Class A shares	-	(10,734)	-	(10,734)	(10,734)	(10,734)
Operating expenses for the period	<b>483,800</b>	361,945	<b>935,761</b>	618,742	(121,855)	(317,019)
<b>Loss per share</b>						
Weighted average number of common shares outstanding	<b>23,143,946</b>	16,556,503	<b>21,903,446</b>	16,380,449		
Basic and diluted	<b>0.02</b>	0.02	<b>0.04</b>	0.04		

The number of options and full warrants outstanding as at July 31st, 2018 and 2017 is not included in the calculation because the effect is anti-dilutive.

### Revenue

There was no revenue generated for the six-month period ended July 31st, 2018 and 2017.

### Expenses

Operating expenses increased by approximately \$122,000 for Q2FY2019 compared to Q2FY2018 and on a year-to-date basis expenses increased from \$619,000 for YTDFY2018 to \$936,000 for YTDFY2019.

All significant expenses have increased due to the research and development activities and animal studies, which were conducted in accordance with the preclinical development plan.

### Research and development costs

For the respective periods, research and development costs consisted of:

	Three months ended		Six months ended		Q2-FY2019 Change	YTD- FY2019 change
	Q2FY2019 July 31, 2018	Q2FY2018 July 31, 2017	YTD FY2019 July 31, 2018	YTD FY2018 July 31, 2017		
	\$	\$	\$	\$		
Salaries and employee benefits	<b>31,826</b>	5,157	<b>66,227</b>	5,157	(26,669)	(61,070)
Research costs	<b>6,940</b>	52,500	<b>27,760</b>	78,504	45,560	50,744
Development costs	<b>40,467</b>	142,945	<b>100,865</b>	272,402	102,478	171,537
Patent prosecution costs	<b>25,026</b>	20,518	<b>49,174</b>	22,743	(4,508)	(26,431)
Amortization – intangible asset	<b>8,076</b>	8,410	<b>16,152</b>	8,410	334	(7,742)
	<b>112,335</b>	229,530	<b>260,178</b>	387,216	117,195	127,038
Investment tax credit	<b>(362)</b>	(143,000)	<b>(362)</b>	(235,078)	(142,638)	(234,716)
	<b>111,973</b>	86,530	<b>259,816</b>	152,138	25,443	(107,678)

We are currently working on three products: Ortho R and M, which are in the development stage, and Ortho C, which is in the research phase. Research costs includes monthly payments related to the contract with Ecole Polytechnique. Development costs includes monthly costs related to the contracts with Ecole Polytechnique and expenses related to studies completed during the period. In August 2017, both parties amended the three contracts. The monthly payments were changed from \$58,333 to \$23,133, which explains the significant decrease in the costs of these three contracts. These activities are overseen by our Vice-President of Product Development, whose compensation and benefits are recorded in Salaries and employee benefits.

- Salaries and employee benefits increased \$27,000 from Q2FY2018 to Q2FY2019 and, on a year-to-date basis, expenses increased from \$5,000 in YTD FY2018 to \$66,000 in YTD FY2019 due to the hire of the VP of Product Development in July 2017.
- Research costs for YTD FY2019 decreased \$51,000 compared to YTD FY2018. The Ortho C contract was completed in May 2018, which represents four months in FY2019 compared to six months in FY2018. Also, the cost of the contract was \$27,760 in YTD FY2019 compared to \$105,000 in YTD FY2018. As for Q2FY2019, the amount of research costs was \$6,940, compared to \$52,500 in Q2FY2018.
- Development costs represent the research contracts paid to Ecole Polytechnique for Ortho R and Ortho M and costs related to the ongoing pilot studies. These contracts amounted to \$16,193 in Q2FY2019 compared to \$122,500 in Q2FY2018 and \$65,000 for YTD FY2019 compared to \$245,000 for YTD FY2018, for an overall decrease of \$180,000 on these research contracts. In Q2FY2019 \$24,274 was paid to the CRO for the pilot studies which ended in Q2FY2019, compared to \$20,445 for the amount paid to consultants for their assistance in Q2FY2018 with the commencement of the pilot studies in the fall of 2017.
- Compared to the Q2FY2018, patent prosecution costs increased by \$4,500 due to fees paid to the agent to defend the claims the Corporation is currently defending with examiners from the United States, Canada and Australia, and for YTD FY2019 compared to YTD FY2018, these costs increased by \$26,000, mainly due to the notice of allowance for two patent families in Europe and translation fees for the respective countries.

The timing of research and development costs was as follows:

	Ortho R	Ortho M	Ortho C	Total
	\$	\$	\$	\$
Expenditures incurred in prior years	944,000	800,000	496,000	2,240,000
Additional expenditures in fiscal 2019	63,852	37,014	27,760	128,626
<b>Total accumulated expenditures</b>	<b>1,007,852</b>	<b>837,014</b>	<b>523,760</b>	<b>2,368,626</b>

### **General and administrative expenses**

For the respective periods, general and administrative expenses consisted of:

	Three months ended		Six months ended		Q2 – FY2019 Change	YTD – FY2019 Change
	Q2FY2019 July 31, 2018	Q2FY2018 July 31, 2017	YTDFY2019 July 31, 2018	YTDFY2018 July 31, 2017		
	\$	\$	\$	\$	\$	\$
Professional and consulting	<b>215,087</b>	130,445	<b>387,022</b>	236,329	(84,642)	(150,693)
Office and administrative	<b>88,543</b>	60,781	<b>145,940</b>	109,253	(27,762)	(36,687)
Travel and promotion	<b>4,004</b>	5,664	<b>11,326</b>	11,938	1,660	612
Share-based compensation	<b>25,532</b>	99,425	<b>48,236</b>	105,081	73,893	56,845
Total	<b>333,166</b>	296,315	<b>592,524</b>	462,601	(36,851)	(129,923)

Overall general and administrative expenses increased by approximately \$37,000 from Q2FY2018 to Q2FY2019 and, on a year-to-date basis, expenses increased from \$463,000 for YTDFY2018 to \$593,000 for YTDFY2019. The increase is mainly due to office and administrative expenses, professional and consulting fees and share-based compensation. All other expenses were consistent with the comparative period of FY2018.

- Office and administrative expenses increased by approximately \$28,000 from Q2FY2018 to Q2FY2019 and increased from \$109,000 for YTD-FY2018 to \$146,000 for YTD-FY2019.

The increase is mainly due to a \$12,000 increase in occupancy costs for YTDFY2019, compared to nil for YTDFY2018 and representing \$6,000 per quarter in FY2019.

Transfer-agent, press release and filing fees increased from approximately \$11,000 in Q2FY2018 to \$21,000 in Q2FY2019 and from \$14,000 for YTDFY2018 to \$25,000 for YTDFY2019. The increase was due to higher securities commissions, transfer agent and reporting costs since the Corporation's shares have been publicly traded and for more press releases during the reporting period. Other expenses such as stationary, courier, telecommunications and general insurance increased by \$13,000 from Q2FY2018 to Q2FY2019 and increased by \$16,000 from YTDFY2018 to YTDFY2019.

- Professional and consulting fees amounted to \$215,000 in Q2FY2019 compared to \$130,000 in Q2FY2018, representing an increase of \$85,000. Concerning the year-to-date, these fees were \$387,000 for YTDFY2019 compared to \$236,000 for YTDFY2018.

Legal and audit fees increased \$26,500 from Q2FY2018 to Q2FY2019 and from \$33,000 for YTDFY2018 to \$78,000 for YTDFY2019. The increase was mainly due to auditors' fees in respect of certain tax matters and to a corporate legal matter.

Investor relations fees increased \$36,500 from Q2FY2018 to Q2FY2019 and from \$37,500 for YTDFY2018 to \$135,000 for YTDFY2019. These increases were due to retaining the services of

other firms. The Corporation is seeking additional guidance and assistance from various firms to create awareness, build shareholder relations, and develop business and market strategies to attract new investors.

Consulting fees increased \$22,000 from Q2FY2018 to Q2FY2019 and, for the year to date, they increased from \$162,000 for YTD FY2018 to \$170,000 for YTD FY2019, representing an increase of \$8,000. The increase is mainly due to fees paid to the CEO and other firms for guidance and assistance on corporate matters.

- Share-based compensation decreased by approximately \$74,000 from Q2FY2018 to Q2FY2019. For the year to date, share-based compensation decreased by \$57,000. The decrease in the respective periods is due to the fact that fewer options were granted in the current period and prior grants were mainly amortized by the end of the past quarter.

On June 19<sup>th</sup>, 2018, the Board granted 200,000 options equally to two consultants at an exercise price of \$0.50.

### **Financial charges**

For the respective periods, financial charges consisted of:

	Three months ended		Six months ended		Q2 – FY2019 Change	YTD – FY2019 Change
	Q2FY2019 July 31, 2018	Q2FY2018 July 31, 2017	YTD FY2019 July 31, 2018	YTD FY2018 July 31, 2017		
			\$	\$		\$
Interest - Short-term debt	10,074	(35,173)	30,984	(12,460)	(45,247)	(43,444)
Interest - Convertible loan	24,638	24,638	48,488	25,885	-	(22,603)
Amortization – Transaction costs	3,949	375	3,949	375	(3,574)	(3,574)
	<b>38,661</b>	<b>(10,160)</b>	<b>83,421</b>	<b>13,800</b>	<b>(48,821)</b>	<b>(69,621)</b>

Overall financial charges increased by approximately \$49,000 from Q2FY2018 to Q2FY2019 and on a year-to-date basis, expenses increased from \$14,000 for YTD FY2018 to \$83,000 for YTD FY2019.

For the respective periods, interest on short term debt consisted of:

	Three months ended		Six months ended		Q2 – FY2019 Change	YTD – FY2019 change
	Q2FY2019 July 31, 2018	Q2FY2018 July 31, 2017	YTD FY2019 July 31, 2018	YTD FY2018 July 31, 2017		
			\$	\$		\$
Interest - Short-term debt	4,758	-	19,156	-	(4,758)	(19,156)
Interest – Manitex	6,228	-	12,801	17,594	(6,228)	4,793
Interest – Ecole Polytechnique	-	(35,402)	-	(30,215)	(35,402)	(30,215)
Others financial charges (income)	(912)	229	(973)	161	1,141	1,134
	<b>10,074</b>	<b>(35,173)</b>	<b>30,984</b>	<b>(12,460)</b>	<b>(45,247)</b>	<b>(43,444)</b>

In FY2019, interest on short-term debt represents interest charged by Manitex Capital Inc. (“Manitex”) on the note payable which bears interest at 12%. In the comparative period of FY2018, the interest charged



by Manitex was for the operating loan bearing interest at 8%, which was converted into equity on April 27, 2017, representing an overall decrease of \$4,790.

In the comparative quarter, the Corporation reversed an interest charge in an amount of \$35,402 or, on a year-to-date basis, \$6,215 for the unpaid contract with Ecole Polytechnique which was never paid.

On September 12, 2017, the Corporation obtained a short-term loan bearing interest at 1.5% per month. In the comparative period of FY2018 there were no such charges.

The increase of \$23,000 is mainly due to the accretion of interest on the Corporation's convertible loan signed on April 27, 2017. At initial recognition, an 18% discount rate was used to calculate the fair value of the liability. Therefore, for the year to date, there were six months of interest charges compared to three months in YTFY2018.

## BALANCE SHEET HIGHLIGHTS

The following table sets forth financial information related to the Corporation's statements of financial position for the periods indicated and should be read in conjunction with the interim condensed financial statements for the three-month period ended July 31st, 2018.

	July 31, 2018 \$	January 31, 2018 \$
Cash	785,686	449,720
Investment tax credits	242,711	160,005
Sales tax receivable and other assets	79,340	39,002
Current assets	1,107,737	648,727
Investment tax credits	-	242,711
Intangible asset	444,180	460,332
Equipment	161,179	159,707
Non-current assets	605,359	862,750
Total assets	1,713,096	1,511,477
Liabilities - current	862,144	757,890
Liabilities - non-current	-	607,239
Common shares	5,410,759	3,842,500
Warrants	801,000	758,380
Contributed surplus	577,583	548,097
Deficit	(5,938,390)	(5,002,629)

## INVESTMENT TAX CREDITS

The amounts and the timing of the recognition of investment tax credits receivable involve a certain degree of estimation and judgment with regards to the eligibility of the research and development expenditures giving rise to the tax credit refunds and to the probability of receiving the amounts. The amounts claimed by the Corporation are subject to review and approval by the tax authorities. The amounts granted may differ from the amounts claimed.

The Corporation recognized investment tax credits on expenditures related to research and development costs. As at July 31st, 2018 and January 31, 2018, the amounts receivable was \$242,711 and \$402,716, respectively. These amounts represent federal and provincial tax credits. In May 2018, the Corporation received an amount of \$160,005 related to the tax credit for the year ended January 31st, 2017.

## **INTANGIBLE ASSETS**

### *INTELLECTUAL PROPERTY*

Ortho is the owner of 4 patent applications filed since 2009. It also owns improvements to the technology discovered through work it funded at École Polytechnique. The current patent portfolio includes the following:

Patent Family No.1: 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;

Patent Family No.2: Novel formulation of physiological biopolymer-inorganic salt solution/blood mixtures for tissue repair;

Patent Family No.3: Freeze-dried polymer compositions for mixing with platelet rich plasma to form implants for tissue repair or compositions for therapeutic intra-articular injections;

Patent Family No.4: Freeze-dried biopolymer scaffolds that form a hydrated microparticle dispersion after contact with blood or blood-derived fluids and stimulate anabolic wound repair processes, including angiogenesis, cell chemotaxis, tissue remodeling, and extracellular matrix deposition;

On August 26, 2016, our patent from Family 2 was issued in the United States. It expires in 2032. On March 8, 2018 our patent from Family 2 received a Notice of Allowance from the European Patent Office. On May 23, 2018 our patent from Family 4 received a Notice of Allowance from the European Patent Office.

During Q2FY2019 there were no additional costs incurred on the intellectual property. The change of \$8,076 represents amortization for the quarter, compared to \$8,410 in Q2FY2018.

## **CURRENT LIABILITIES**

Current liabilities are comprised of accounts payable in the amount of \$74,559 compared to \$245,942 as at January 31st, 2018, short-term debt in the amount of \$131,432 compared to \$511,948 as at January 31st, 2018, and the convertible loan in the amount of \$656,153 compared to \$607,239 as at January 31st, 2018.

Short-term debt was comprised of:

### (a) Note payable

On July 28th, 2017, the Corporation and Manitex signed an unsecured note payable in the amount of \$224,737 bearing interest at 12% and maturing on October 31st, 2018. The amounts owed on the note payable as at July 31st, 2018 and January 31st, 2018 were \$131,432 and \$238,628, respectively. On July 19th, 2018, the Corporation issued 300,000 shares at the deemed price of \$0.40 per share in conjunction with a private placement that closed on the same date. In addition, there were charges of \$12,804 for accrued interest on the note payable. At maturity the amount to be paid to Manitex will be \$135,405.

### (b) Short-term loan

On September 12th, 2017, the Corporation signed a short-term loan agreement to finance its investment tax credits in an amount of \$278,700. The loan is secured by a first-rank moveable hypothec on all of its assets, and bears interest at a fixed rate of 1.5% per month. As at July 31st, 2018, the Corporation had repaid the entire loan to the creditor.

(c) Convertible loan

During the period, the convertible loan was reclassified to short-term due to its maturity date of February 1st, 2019. As at January 31st, 2018, the loan was presented as a non-current liability.

The convertible loan due to Manitex as at April 30th, 2018 amounted to \$631,090 compared to \$607,239 as at January 31st, 2018. The change was due to the accretion of interest in an amount of \$23,851. At maturity the amount to be paid to Manitex will be \$705,863, which is based on a principal of \$600,000 and 10% interest.

## SUMMARY OF QUARTERLY RESULTS

The following table sets out the Corporation's selected unaudited quarterly financial information for the eight quarters ended July 31st, 2018. This information is derived from unaudited quarterly financial statements prepared by management and in accordance with IFRS and is expressed in Canadian dollars. 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.

	FY 2019 Q2 \$	FY 2019 Q1 \$	FY 2018 Q4 \$	FY 2018 Q3 \$	FY 2018 Q2 \$	FY 2018 Q1 \$	FY 2017 Q4 \$	FY 2017 Q3 \$
<b>R&amp;D costs</b>	<b>111,973</b>	<b>147,842</b>	<b>318,399</b>	<b>263,358</b>	<b>87,473</b>	<b>65,608</b>	<b>41,608</b>	<b>236,109</b>
<b>G&amp;A expenses</b>								
Professional and consulting fees	215,087	171,935	133,088	197,380	130,445	105,884	124,903	83,365
Office and administrative	88,543	57,397	68,158	74,147	59,838	49,415	44,869	89,123
Travel and promotion	4,004	7,322	7,271	10,141	5,664	6,274	7,557	13,755
Share-based compensation	25,532	22,704	48,768	51,073	99,425	5,656	(19,003)	40,473
<b>Total G&amp;A</b>	<b>333,166</b>	<b>259,358</b>	<b>257,285</b>	<b>332,741</b>	<b>295,372</b>	<b>167,229</b>	<b>158,326</b>	<b>226,716</b>
<b>Financial expenses (income)</b>	<b>38,661</b>	<b>44,760</b>	<b>65,163</b>	<b>47,897</b>	<b>(10,160)</b>	<b>23,960</b>	<b>40,712</b>	<b>10,727</b>
<b>Change in fair value of Class "A" shares</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>118,067</b>	<b>(10,734)</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Net loss for the quarter</b>	<b>483,800</b>	<b>451,961</b>	<b>640,848</b>	<b>762,063</b>	<b>361,951</b>	<b>256,797</b>	<b>240,646</b>	<b>473,552</b>
Loss per share								
Basic and diluted:	0.02	0.02	0.04	0.02	0.02	0.01	0.03	0.03

R&D is defined as Research and development costs and G&A is defined as General and administrative expenses.

There are three main categories of expenses: Research and development costs, general and administrative expenses and financial expenses.

Research and development costs have fluctuated from quarter to quarter and are presented net of investment tax credits ("ITC's"), which were accrued on a quarterly basis when the amounts were significant. The total amounts for FY2018 and FY2017 were \$235,078 and \$245,124, respectively, and nil for the quarters in FY2019, because the amounts were deemed not significant. For the quarters from Q2FY2017 to Q3FY2018, the monthly amount paid to Ecole Polytechnique for the research agreements was \$58,133 and, commencing in Q3FY2018, the amount was reduced to \$23,133 per month. In addition, in late Q2FY2018, the Corporation hired a VP of Product Development. In Q3FY2018, the Corporation commenced three preclinical studies in order to solidify its IND submission to the FDA. Two of the three studies were completed in Q4FY2018 and the six-month pilot study was completed in Q2FY2019, which explains the significant increase in R&D costs in the respective quarters compared to the other quarters of FY2017. As for Q3FY2017, the Corporation performed preclinical studies for the early preclinical plan and

incurred costs to prosecute the patent family in Canada, the United States, Europe, Australia and other relevant countries.

General and administrative expenses have fluctuated from quarter to quarter. Included in professional and consulting fees are recurring expenses for audit and tax related matters, in-house counsel, fees paid to investor relations firms and fees paid to the CEO. The fluctuation was due to fees paid to other consultants for assistance with financing, business strategies and corporate advisory functions and additional fees paid to the CEO based on the capital raised.

Office and administrative expenses include salaries and benefits paid to one employee and were stable for the quarter. Transfer agent and filing fees increased in each period commencing in January. The Corporation was paying \$6,000 per quarter in occupancy costs. Other expenses, such as insurance, office and telecommunications expenses, have been relatively stable and had no significant impact on the overall amount.

Share-based compensation increased during the quarters in FY2018 compared to FY2019 and FY2017. This was mainly due to the options granted to the new CEO in Q2FY2018 and to a new employee and members of the board and the advisory board, which form part of their compensation. In Q2FY2019, the Corporation granted options to two consultants for services to be rendered over the next 18 months.

Financial expenses increased significantly in FY2018 compared to FY2017, due to a new short-term loan bearing interest at a rate of 1.5% per month and the convertible loan, recorded at an interest rate of 18% to reflect its market value at initial recognition. In Q2FY2018, the financial income was due to a reversal of the interest accrued on the settlement of the debt to École Polytechnique.

In addition, the non-cash item, a net change in the fair value of Class "A" shares in a net amount of \$107,333, resulted from the shares being reclassified from a liability to equity. An equity instrument shall be measured at the carrying value of the financial liability at the date of reclassification. As of Q3FY2018, the shares had been reclassified as equity at fair value.

## CASH FLOWS, LIQUIDITY AND CAPITAL RESOURCES

### CASH FLOWS:

#### Sources and Uses of Cash

For the six-month periods ended July 31	2018	2017
	\$	\$
Provided by (used in):		
Operating activities	(813,869)	(816,222)
Investing activities	(1,472)	(36,410)
Decrease in cash before financing activities	(815,341)	(852,632)
Cash received from operating loan	-	81,100
Cash received from equity financing	1,504,000	1,232,500
Proceeds from exercised warrants	9,863	-
Proceeds from exercised options	2,500	-
Payment of debt issue costs	-	(1,500)
Payment of interest on short-term debt	(19,156)	-
Repayment of short-term debt	(278,700)	-
Payment of share issue costs	(67,200)	(51,375)
Increase in cash	335,966	408,093
Cash, beginning of period	449,720	7,366
Cash, end of period	785,686	415,459

At the end of Q2FY2019, the Corporation had cash resources of \$786,686 compared to \$415,459 at the end of Q2FY2018. During Y2FY2019, the Corporation closed a financing in the amount of approximately \$1,437,000, net of issue costs of \$67,200, received proceeds from the exercise of equity instruments in the amount of \$12,363, and used approximately \$814,000 to fund operating activities and another \$1,500 to purchase equipment. In addition, the Corporation repaid the short-term loan of \$278,700 and paid interest of \$19,156. During Q2FY2018, the Corporation closed a financing in the amount of approximately \$1,181,000, net of issue costs of \$51,000. The Corporation used approximately \$816,000 of this financing to fund operating activities and another \$36,410 to pay for intellectual property as per the agreement with Polyvalor. In addition, the Corporation received \$81,100 from Manitek Capital as an increase in its operating loan, which was subsequently converted into equity and a convertible debenture.

At the end of the quarter, these cash resources were insufficient to sustain operations through FY2019 in terms of funding operating activities and continuing the preclinical development plan with the CMO and CRO. The Corporation continues to seek financing from institutional life science investors and, in addition to the Canadian market, is looking to penetrate the U.S. market.

### Future financing

At the close of the business day on July 31st, 2018, Ortho RTI had 4,214,714 warrants outstanding exercisable at \$0.70 and 44,113 warrants outstanding exercisable at \$0.50. These warrants are currently in-the-money. All of the warrants contain a trigger provision that provides the Corporation with the discretionary ability to accelerate the expiry date to a period of 30 days: if the Corporation's weighted average share price for 30 consecutive trading days equals or exceeds \$1.00 per share, the Corporation may give notice to the warrant holders that they must exercise their warrants within a period of 30 days from the date of receipt of such notice. Any warrants not exercised during this reduced exercise period will expire.

The extent to which these warrants are exercised will be a function of the market price of the Corporation's underlying common shares and investors' view of the opportunity for shareholder value creation over the investment time for each individual investor. If the acceleration clause is exercised, the maximum inflow of cash to the Corporation would be approximately \$2,972,000. 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 support operations going forward. The current focus in this regard is on private placements with accredited and institutional investors.

### LIQUIDITY AND CAPITAL RESOURCES

	July 31, 2018 \$	January 31, 2018 \$
Cash	785,686	449,720
Working capital <sup>(i)</sup>	245,593	(109,163)
<b>Total assets</b>	<b>1,713,096</b>	<b>1,511,477</b>

(i) Working capital is a measure of current assets less current liabilities.

The Corporation's primary objective with respect to its capital management is to ensure that it has sufficient financial resources to meet its financial obligations. The current working capital deficiency is being addressed by the Corporation and its Board of Directors.

To secure the additional capital necessary to fund its working capital and development projects, the Corporation is actively attempting to raise funds through the issuance of equity or by securing strategic partners. Management continues to seek new investors from financial institutions and accredited investors.

Over the next 12 months, the Corporation has the obligation to repay short-term debt in the amount of approximately \$915,827, including interest payments to be made at the contractual rate, and to pay its sublease in the amount \$24,000.

Over the next 12 months, the Corporation's development activities will be focused on completing the manufacturing of the Ortho R product and commencing its animal pivotal preclinical trials following good laboratory practice, with a CRO. The Corporation's use of available funds over the coming year is of utmost concern to the Board, and revised spending budgets have been prepared to postpone development activities and reduce some administrative expenses, should the private financing through share issues or debt be insufficient to fund the business plan. These activities can be postponed, and we do not believe that these delays would materially impact the potential for the product or the Corporation. The Corporation can also delay the prosecution of its patents. In doing so, the Corporation is not giving up any of its rights or the protection of its intellectual property, as the patent authorities have built in such delays into the patent regulations, and companies are afforded the opportunity to delay the prosecution of patents for confidentiality and strategic reasons.

### ***Discussion of operating cash requirements***

All four products in the Corporation's current portfolio will require a significant investment to increase their market value (through, for example, clinical trials) to attract a strategic partner. We currently estimate that an investment of at least \$35 million will be required over time to complete the research and development process, including regulatory approvals and manufacturing validations.

There are several areas where duplication between product lines can be avoided, for example in the manufacture of the chitosan material, which is common across our product platform. We therefore do not need to replicate manufacturing capability, or the associated costs, for each of the four products.

Ortho-R is in a pure development phase and represents our lead product for commercialization. We anticipate that human pilot clinical trials may start in the third quarter of 2020, once the Investigational New Drug ("IND") application has been approved. The current stage of the program is concentrated on ensuring that all preclinical activities are complete: these preclinical activities include formal toxicology testing, pivotal animal efficacy study(ies), and the transfer of the manufacturing process to a contract manufacturing organization. All the preclinical activities have commenced, and we anticipate that they can all be accomplished with another \$2.8 million in expenditures up to the IND approval.

Ortho-M is the Corporation's second candidate and is also in a development phase. The large animal preclinical model studies are complete. We anticipate a pathway and plan similar to that for Ortho-R, and management is currently evaluating the estimated commencement of the pivotal animal efficacy study(ies). This will require an investment of approximately \$1 million for submission of an IND application.

Ortho-C is in the research and discovery phase. The Corporation (through its ongoing funding) will continue to investigate possible formulations and conduct small and large animal research studies to investigate possible efficacy in articular cartilage repair.

Ortho-V is a discovery and feasibility project whose funding will come from the same research agreement with École Polytechnique covering the development of Ortho-M. To date, minimal funds have been applied to this project.

In order to maintain the research and development activities for these four projects, we are currently in discussions with École Polytechnique to continue developing the projects over the next three years.

### **COMMITMENTS**

The Corporation has entered into the following commitments:

a) As per the Intellectual Property Assignment and Technology Transfer Agreement, when the product is commercialized, the Corporation must make non-refundable payments to Polyvalor equal to 1.5% of net sales.

b) Effective January 1, 2018, the Corporation signed a sublease agreement for the period from January 1, 2018 to December 31, 2021. The sublease agreement does not contain a contingent rent clause, and both parties may terminate the sublease agreement by giving a two-month notice after the initial term of 6 months. The remaining amounts to be paid are \$82,000 or \$24,000 for the next 3 years and \$10,000 for the fourth year.

## OFF-BALANCE SHEET ARRANGEMENTS

The Corporation does not have any off-balance sheet arrangements.

## TRANSACTIONS WITH RELATED PARTIES

The following table details the related party transactions presented in the statements of loss for the periods ended:

	<b>July 31, 2018</b>	<b>July 31, 2017</b>
	<b>\$</b>	<b>\$</b>
<i>Transactions with key management members and members of the Board of Directors:</i>		
Salaries and employee benefits	<b>83,261</b>	83,216
Share-based compensation to employees and directors	<b>35,076</b>	92,142
Consulting fees charged by a director and the acting CEO	<b>150,080</b>	129,650
<i>Transactions with a family member of a director and the acting CEO</i>		
Consulting fees charged by the family member	-	15,000
<i>Transactions with Manitex, a shareholder of the Corporation:</i>		
Interest charged by Manitex	<b>61,292</b>	43,475
Consulting fees charged by Manitex	-	8,100
<i>Transaction with École Polytechnique, a partner of Polyvalor:</i>		
Reversal of interest accrued	-	(6,215)
Research and development costs	<b>71,714</b>	350,000

Compensation of key management includes directors and the Vice-President of Finance and Chief Financial Officer.

The following table details the related party transactions presented in the statements of financial position as at:

	<b>July 31, 2018</b>	<b>January 31, 2018</b>
	<b>\$</b>	<b>\$</b>
Accounts payable and accrued liabilities due to a director and acting CEO	-	<b>10,000</b>

All other related party transactions are disclosed in the respective notes of the financial statements.

## USE OF ACCOUNTING ESTIMATES AND JUDGMENTS

The application of the Corporation's accounting policies requires management to use estimates and judgments that can have a significant effect on the revenues, expenses, comprehensive loss, assets and liabilities recognized and disclosures made in the financial statements.

Management's best estimates concerning the future are based on the facts and circumstances available at the time estimates are made. Management uses historical experience, general economic conditions and assumptions regarding probable future outcomes as the basis for determining estimates. Estimates and

their underlying assumptions are reviewed periodically and the effects of any changes are recognized immediately. Actual results could differ from the estimates used.

Management's budget and strategic plans are fundamental information used as a basis for the estimates necessary to prepare financial information. Management tracks performance as compared to the budget, and significant variances in actual performance are a key trigger to assess whether certain estimates used in the preparation of financial information must be revised.

Please refer to Note 3 of the annual audited financial statements 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.

## **CHANGES IN ACCOUNTING POLICIES INCLUDING INITIAL ADOPTION**

The IASB issued new standards that were effective for the Corporation's fiscal year beginning February 1, 2018. The following standards were adopted on February 1, 2018:

### **(a) IFRS 9 Financial Instruments**

The final version of IFRS 9, Financial Instruments ("IFRS 9"), was issued by the IASB in July 2014 and will replace IAS 39, Financial Instruments: Recognition and Measurement. IFRS 9 introduces a model for classification and measurement, a single, forward-looking expected loss impairment model and a substantially reformed approach to hedge accounting. The new single, principle-based approach for determining the classification of financial assets is driven by cash flow characteristics and the business model in which an asset is held. The new model also results in a single impairment model being applied to all financial instruments, which will require more timely recognition of expected credit losses. It also includes changes in respect of an entity's own credit risk in measuring liabilities elected to be measured at fair value, so that gains caused by the deterioration of an entity's own credit risk on such liabilities are no longer recognized in profit or loss. IFRS 9, which is to be applied retrospectively, is effective for annual periods beginning on or after January 1, 2018 and is available for early adoption. In addition, an entity's own credit risk changes can be applied early in isolation without otherwise changing the accounting for financial instruments. The adoption of the amendment did not have a material impact on these financial statements.

### **(b) IFRS 15 Revenue from Contracts with Customers**

In May 2014, the IASB issued IFRS 15, Revenue from Contracts with Customers. The objective of this new standard is to provide a single, comprehensive revenue recognition framework for all contracts with customers to improve the comparability of the financial statements of companies globally. This new standard contains principles that an entity will apply to determine the measurement of revenue and the timing of its recognition. The underlying principle is that an entity will recognize revenue to depict the transfer of goods or services to customers at an amount that the entity expects to be entitled to in exchange for those goods or services. This new standard is effective for annual periods beginning on or after January 1, 2018. The adoption of the amendment did not have a material impact on these financial statements.

## **STANDARDS ISSUED BUT NOT YET EFFECTIVE**

The information is provided in Note 2e) of the interim condensed financial statements.

## **FINANCIAL INSTRUMENTS**

All financial instruments are recognized when the Corporation becomes a party to the contractual provisions of the financial instrument and are initially measured at fair value plus transaction costs, except for financial assets and financial liabilities carried at fair value through profit or loss, which are measured initially at fair value. Financial assets are derecognized when the contractual right to the cash flows from the financial assets expire, or when the financial asset and all substantial risks and rewards are transferred. An extended



description of the Corporation's financial instruments and their fair values is provided in Note 9 of the interim condensed financial statements.

## SUBSEQUENT EVENTS

On August 28, 2018, the Corporation signed a letter of agreement with Ecole Polytechnique for a three-year research contract for a total amount of \$886,650 payable over 3 years for an annual amount of \$295,550 commencing September 1, 2018. The details of this contract were not yet fully determined at the reporting date.

## RISK MANAGEMENT

The Corporation's activities expose it to financial risks: market risk, specifically to cash flow, and fair value interest rate risk and liquidity risk. The Corporation's overall risk management program focuses on the unpredictability of the financial market and seeks to minimize potential adverse effects on the Corporation's financial performance. The Corporation does not use derivative financial instruments to hedge these risks.

Management determined that the Corporation is not exposed to currency and credit risk arising from these financial instruments.

### Market risk

#### (a) Credit risk

Credit risk arises from cash deposited with a financial institution. The Corporation reduces this risk by dealing with creditworthy financial institutions.

#### (b) Market risk

##### (i) Cash flow and fair value interest rate risk

The Corporation is exposed to fair value interest rate risk due to its note payable and convertible debenture negotiated at a fixed rate.

##### (ii) Currency risk

The Corporation has cash and accounts payable and accrued liabilities denominated in U.S. dollars. The Corporation does not hold financial derivatives to manage fluctuations in these risks. However, the amount is deemed to be immaterial for the presented periods.

#### (c) Liquidity risk

Liquidity risk is the risk that the Corporation will not be able to meet its obligations as they fall due. The following are the contractual maturities of financial liabilities as at:

<b>July 31, 2018</b>	<b>Carrying Value</b>	<b>Contractual cash flows</b>	<b>Less than 60 days</b>	<b>60 days to 12 months</b>	<b>More than 12 months</b>
	\$		\$	\$	\$
Financial liabilities					
Accounts payable and accrued liabilities	74,559	74,559	47,287	27,272	-
Short term liabilities *	131,432	135,405	-	135,405	-
Convertible loan *	656,153	705,863	-	705,863	-
<b>Total</b>	<b>862,144</b>	<b>915,827</b>	<b>47,287</b>	<b>868,540</b>	<b>-</b>

***(d) Capital risk management***

The Corporation's objective when managing capital is to maintain its ability to continue as a going concern in order to provide returns for the shareholders and benefits for other stakeholders. The Corporation includes equity, comprised of issued common shares, warrants and contributed surplus, in the definition of capital. The Corporation's primary objective with respect to its capital management is to ensure that it has sufficient financial resources to meet its financial obligations. To secure the additional capital necessary to pursue these plans, the Corporation will attempt to raise additional funds through the issuance of equity or by securing strategic partners. The Corporation is not subject to any externally imposed capital requirements.