

# Immunotherapy approaches to breast cancer management

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# **BriaCell Therapeutics Corp.**

Management's Discussion and Analysis For the Three Months Periods Ended October 31, 2018

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

### 1. MANAGEMENT'S DISCUSSION AND ANALYSIS

The following discussion and analysis is management's assessment of the results and financial condition of BriaCell Therapeutics Corp. (collectively, BriaCell", "we" or the "Company").

The following information should be read in conjunction with the audited consolidated financial statements for the year ended July 31, 2018 and the notes to those financial statements, all of which are available on BriaCell's issuer profile on SEDAR at www.sedar.com and on the Company's website at www.briacell.com.

The date of this management's discussion and analysis ("MD&A") is December 28, 2018. The Company's comparative amounts in this MD&A have been prepared in accordance with International Financial Reporting Standards ("IFRS"). All dollar amounts are stated in Canadian dollars unless otherwise indicated.

Statements in this report that are not historical facts are forward-looking statements involving known and unknown risks and uncertainties, which could cause actual results to vary considerably from these statements. Readers are cautioned not to put undue reliance on forward-looking statements.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION

This MD&A contains "forward-looking information" within the meaning of applicable Canadian securities legislation ("forward-looking information"). Such forward-looking information involves known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements of the Company to be materially different from any future results, performance or achievements expressed or implied by the forward-looking information. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date the statements were made, and readers are advised to consider such forward-looking statements in light of the risks set forth below and as detailed under **RISKS AND UNCERTAINTIES** in this MD&A.

Although the Company has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking information, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Forward-looking information contained herein is given as of the date of this MD&A and the Company disclaims any obligation to update any forward-looking information, whether as a result of new information, future events or results, except as may be required by applicable securities laws. There can be no assurance that forward-looking information will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking information.

Risk factors affecting the Company include risks associated with the undertaking of a new business model; share dilution; a history of operating losses; early stages of development; ability to manage growth; unproven market; manufacturing, pharmaceutical development and marketing capability; preclinical studies and initial clinical trials are not necessarily predictive of future results; raw materials and product supply; the need for additional capital and access to capital markets; competition; intellectual property; litigation to protect the intellectual property; dependence upon management; governmental regulation and litigation risk the Company's ability to attract and retain skilled employees and contractors, and changes in foreign currency exchange rates.

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## 2. DESCRIPTION OF BUSINESS

BriaCell Therapeutics Corp. ("BriaCell" or the "Company"), was incorporated under the Business Corporations Act (British Columbia) on July 26, 2006 and is listed on the TSX Venture Exchange ("TSXV"). The Company is developing a new therapy for advanced breast cancer. The address for the Company's registered office is located at Suite 300 – 235 West 15<sup>th</sup> Street, West Vancouver, British Columbia, V7T 2X1.

On July 24, 2017, the Company entered into a definitive share exchange agreement (the "Share Exchange Agreement") with its wholly-owned subsidiary, Sapientia Pharmaceuticals, Inc. including all the shareholders of Sapientia. Sapientia, a biotechnology company based in Havertown, PA, is developing novel targeted therapeutics for multiple indications including several cancers and fibrotic diseases.

Pursuant to the terms of the Share Exchange Agreement, BriaCell Therapeutics Corp. agreed to acquire from the Sapientia Shareholders all of the issued and outstanding shares in the capital of Sapientia as at the date hereof in consideration to the Sapientia Shareholders, pro rata, of an aggregate of 2,500,002 common shares in the capital of BriaCell (the "Transaction"), which were issued on September 5, 2017. As part of the Transaction, BriaCell acquired all rights, including composition of matter patents, and preclinical study data to a novel therapeutic technology platform, known as protein kinase C delta (PKC δ) inhibitors, which represents a unique, highly-targeted approach to treat cancer and potentially to boost the immune system.

### 3. OPERATIONS REVIEW

### Overview

BriaCell is an immuno-oncology biotechnology company with a strong focus on cancer immunotherapy. Immunotherapies have come to the forefront in the fight against cancer. They harness the body's own immune system to recognize and destroy cancer cells. BriaCell owns the US patent to SV-BR-1-GM (Bria-IMT<sup>TM</sup>), a whole-cell targeted immunotherapy for cancer (U.S. Patent No. 7,674,456), as well as patents related to PKCδ inhibitors (U.S. Patent Nos. 9,364,460 and 9,572,793). The Company is currently advancing its targeted immunotherapy program by prioritizing a Phase I/IIa clinical trial with Bria-IMT<sup>TM</sup> in combination with an immune checkpoint inhibitor and a companion diagnostic test, BriaDX<sup>TM</sup>, to identify patients likely benefitting from Bria-IMT<sup>TM</sup>. The first patient dosing in the "combination therapy" clinical trial occurred in September 2018.

The Company has demonstrated an early proof of principle with Bria-IMT™ without an immune checkpoint inhibitor and is intent on building upon these results to further develop Bria-IMT™ through additional clinical testing. The results of two previous Phase I clinical trials (one with a precursor of the Bria-IMT™ targeted immunotherapy and the other with Bria-IMT™) have been encouraging in terms of both safety and efficacy in patients with stage IV breast cancer who had failed other available therapies including various kinds of chemotherapy. Most notably, a patient with recurrent metastases developed a remarkable response after Bria-IMT™ injections. A lesion in the lung regressed totally and near-complete responses were seen in other lesions. Four months after the last Bria-IMT™ injection, per FDA guidelines, the patient was found to have relapsed, both locally and in distant areas including the brain. Within 2 months after restarting Bria-IMT™, all areas of involvement showed significant regressions, including regression of multiple lesions in the brain. This patient was found to allele-match¹ with Bria-IMT™ at *HLA-DRB3*, a human leukocyte antigen (HLA) gene implicated in helper T cell activation and as such potentially involved in the generation of tumor-directed cellular and/or humoral (antibodies) immune responses.

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<sup>&</sup>lt;sup>1</sup> HLA alleles correspond to HLA types and are typically used to match patients with organs when they are receiving an organ transplant (like a kidney transplant).

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More recently, additional breast cancer patients have been dosed with Bria-IMT™, of which some have experienced mixed responses (tumor regression at some sites but at others).

These are very preliminary results but suffice to demonstrate clearly an unequalled biological activity for inducing tumor rejection, an excellent safety profile, and validate the initial preliminary findings. Furthermore, the data adds importantly to a proposed mechanism of action in that all patients with tumor regressions to date have had at least 1 HLA allele match with Bria-IMT™. This is an important confirmation that Bria-IMT™ can be effective in shrinking metastatic breast cancer, especially in patients who match at certain HLA alleles.

# Significant financial developments during period

1,431,219 shares were issued at \$0.10 per share in respect of the partial conversion of certain Convertible Notes. Upon exercise of these Convertible Notes, Noteholders received 1,431,219 warrants with an exercise price of \$0.14, expiring within three years.

1,000,000 shares were issued in respect of 1,000,000 warrants that were exercised at an exercise price of \$0.14 for gross proceeds of \$140,000.

# Mechanism of Action of Bria-IMT™ and Bria-OTS™

The Company is particularly interested in understanding the mechanism of action (MoA) of Bria-IMT™. Thus, Research has been and will be directed at this concept. By gaining an understanding of how and why Bria-IMT™ has been successful in eliciting promising clinical results, the Company may be able to better target those who will have a greater chance of benefitting from it. Dr. Markus Lacher, Senior Director of Research and Development, developed a model for Bria-IMT™'s MoA and submitted this in a manuscript for publication to Frontiers in Immunology, a leading journal in the immunology space. As outlined below, the manuscript was accepted for publication (published in mid-May 2018). In short, in collaboration with colleagues at outside institutions, the Company has identified evidence that Bria-IMT™ cells can directly activate T cells, an important subset of immune cells implicated in tumor destruction by immunotherapeutic strategies. Importantly, tumor-directed immune responses were observed in patients with HLA matches with Bria-IMT™. HLA molecules are components of the immune system involved in the presentation of antigens to patient T cells and as such in the activation of T cells. Since the most pronounced tumor-directed clinical responses were observed in HLA-matched patients, HLA types are determined from cells from each patient entering BriaCell's Phase I/IIa clinical trials (see below); however, at this point, patients not matching with Bria-IMT<sup>TM</sup> are not (yet) excluded from the trials. HLA typing is done from buccal (inner cheek) swabs at the Terasaki Foundation Laboratory/Terasaki Research Institute in Los Angeles, CA. To maximize future patient coverage, BriaCell is developing its next-generation cellbased immunotherapy platform (Bria-OTS™), which in essence is a series of SV-BR-1-based cell lines engineered to express HLA alleles (HLA types) expected to be present in the vast majority of US patients.

# <u>Patent Applications to Protect Additional Cancer Immunotherapies and BriaCell's Companion</u> Diagnostic

As announced in a press release dated March 7, 2017, covering findings pertinent to the Bria-OTS<sup>TM</sup> (therapeutic) and BriaDX<sup>TM</sup> (companion diagnostic) programs, the Company filed an international patent application under the Patent Cooperation Treaty (PCT) with the United States Patent and Trademark Office (USPTO) - "WHOLE-CELL CANCER VACCINES AND METHODS FOR SELECTION THEREOF" (PCT/US2017/019757). This PCT application entered the National Phase in the second half of 2018 and encompasses two provisional patent applications filed with the USPTO in 2016.

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On November 13, 2017, BriaCell disclosed the allowance by the US Patent and Trademark Office (USPTO) and also the European Patent Office (EPO) of two patent applications related to protein kinase C delta (PKC $\delta$ ) inhibitor technology, titled "PKC Delta Inhibitors for use as Therapeutics". In a related matter, BriaCell announced the advancement of its small molecule program based on its proprietary PKC $\delta$  inhibitor technology. The PKC $\delta$  inhibitor technology, which includes the entire PKC $\delta$  inhibitor patent portfolio, was recently acquired by BriaCell from Sapientia Pharmaceuticals Incorporated (Sapientia). The technology, developed by Douglas V. Faller, MD, PhD, and Robert M. Williams, PhD, includes potent and selective small molecule inhibitors of PKC $\delta$ , an enzyme involved in the development of certain cancers. It has been shown that PKC $\delta$  inhibitors cause the breakdown of RAS proteins, involved in cancer cell growth, and hence cause the cancer cells to stop dividing and die. In addition, by boosting the immune system to recognize and kill cancer cells, PKC $\delta$  inhibitors may act as a type of immunotherapy.

# <u>Development of Companion Diagnostic Test (BriaDX™) for Bria-IMT™</u>

The BriaDX<sup>™</sup> program has focused on analyzing specimens obtained from patients previously treated with Bria-IMT™ along with co-analysis of previously manufactured lots of Bria-IMT™ and runs in parallel to the Company's Phase I/IIa clinical trials (see below). The goal of the BriaDX™ program is a predictive test (BriaDX™) that determines Bria-IMT™ responsiveness using, for instance, patient blood or buccal swabs as test input. Currently, HLA typing is an important aspect of BriaDX™, among others emphasized in a press release dated January 3, 2018: Six patients were treated during 2017 with Bria-IMT™ therapy. One patient, a 73-year-old woman, had breast cancer diagnosed in 1995. She developed liver metastases in 2010, and then 20 lung metastases in 2017. Prior treatments included surgery, radiation therapy, hormonal therapy and seven rounds of chemotherapy with 8 different chemotherapy agents. She received 5 cycles of Bria-IMT™ over the first 3 months of treatment, then 3 additional cycles over the following 3 months (6 months total). Evaluation was performed after 3 months and 6 months. After 3 months, despite the extensive prior therapy, her scans noted that, "there has been a clear response seen in all 20 multiple bilateral pulmonary nodules" indicating that all lung metastases had disappeared or decreased in size, with residual lesions presumably representing scarring. This response was maintained after 6 months of treatment with Bria-IMT™. The liver tumors were stable to slightly increased at 3 months, and then progressed after 6 months. Similar to the patient reported previously by Dr. Charles Wiseman, BriaCell's Scientific Founder, in a proof-of-concept/pilot clinical study, this patient is a match with Bria-IMT™ at specific biomarkers (HLA-A and HLA-DRB3). This is highly significant, as it supports our BriaDX<sup>™</sup> hypothesis that these biomarkers can be used to select the patients most likely to respond to Bria-IMT<sup>™</sup> therapy.

#### Bria-IMT™Mechanism of Action Addressed in Major Immunology Journal

As outlined in press releases (dated April 3, 2018 and May 21, 2018), the Company announced the acceptance and publication of a manuscript describing the proposed mechanism of action of the Company's lead product candidate, Bria-IMT<sup>TM</sup>, in Frontiers in Immunology, which is among the top 10 most-cited Immunology journals worldwide. The findings detailed in the paper provide a rationale for the encouraging clinical results observed with Bria-IMT<sup>TM</sup> in current and past clinical testing. Bria-IMT<sup>TM</sup>, also known as SV-BR-1-GM, has caused remarkable reduction of tumor size in some patients with advanced metastatic breast cancer. Understanding Bria IMT<sup>TM</sup>'s mechanism of action is extremely important, not only for developing further clinical refinements; it may shed light on basic immune mechanisms important in many other areas.

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The peer-reviewed paper provides evidence for the unique immune-enhancing activity of Bria-IMT™, which is believed to set the Bria-IMT™ approach apart from all other similar therapies. Bria-IMT™ contains a number of factors, in particular HLA-Class II molecules, i.e., specific markers that distinguish the body's own cells from cells recognized by the body as foreign. These factors directly activate CD4+ "Helper" T cells, a key component of the immune system, which may produce a vigorous attack on tumor cells resulting in clinical tumor regressions (i.e., reduction in the tumor size).

The full-length manuscript was published mid-May 2018 and is available under <a href="https://www.frontiersin.org/articles/10.3389/fimmu.2018.00776/full">https://www.frontiersin.org/articles/10.3389/fimmu.2018.00776/full</a> (accessed 14 December 2018).

Bria-IMT™ Phase I/IIa clinical trial (Expanded Clinical Trial).

### Clinical Operations – FDA Clearance

On March 10, 2015, BriaCell submitted, and received approval for its protocol from the FDA, summarizing plans to apply Bria-IMT<sup>TM</sup> to additional advanced-stage breast cancer patients. Thereafter, the clinical protocol had been substantially modified and was resubmitted to the FDA in September 2016. As the need for yet additional changes became apparent, the Protocol has thereafter been further modified and was re-submitted to the Western Institutional Review Board (WIRB) and thereafter to the FDA. Similarly, as addressed in a press release dated February 6, 2017, the Company completed a Chemistry, Manufacturing, and Controls (CMC) amendment required to initiate the planned Phase I/IIa clinical trial. As outlined in a press release dated March 15, 2017, the Company thereafter received FDA clearance to initiate its planned expanded clinical trial. Additional amendments have all received FDA approval and the study has recruited over 30 patients with over 25 having been dosed to date.

# Clinical Operations - Clinical Sites

Enrollment in the Phase I/IIa "monotherapy" study with Bria-IMT™ (ClinicalTrials.gov Identifier: NCT03066947) was completed in November 2018. All patients have either ceased treatment or "rolled over" to the "combination therapy" trial (Combination Study of SV-BR-1-GM in Combination With Pembrolizumab, ClinicalTrials.gov Identifier: NCT03328026). To date (December 14, 2018). This study is now directly enrolling patients. The following clinical sites are open for patient enrollment in the "combination therapy" trial:

- St. Joseph Heritage Healthcare, Santa Rosa, CA; Principle Investigator: Dr. Jarrod P Holmes, M.D.
- Providence Regional Medical Center, Everett, WA; Principle Investigator: Dr. Jason Lukas, MD, PhD
- Jefferson Breast Care Center, Philadelphia, PA; Principle Investigator: Dr. Saveri Bhattacharya,
   DO
- Sylvester Comprehensive Cancer Center, University of Miami, FL: Principal Investigator: Dr. Carmen J Calfa, MD
- Cancer Center of Kansas (CCK): Principle Investigator: Dr. Shaker R. Dakhil, MD. Under the direction of Dr. Dakhil, the Cancer Center of Kansas lists 16 offices, and 13 Sub Investigators.

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Clinical Operations - Safety and Efficacy Data

As outlined in press releases dated January 3, 2018 and January 31, 2018, BriaCell has obtained early evidence of efficacy and safety of Bria-IMT<sup>TM</sup> (Bria-IMT<sup>TM</sup>): Twenty patients have received inoculations since the trial began in early 2017, with the observation that the regimen was well tolerated, had few side effects, and appears safe. Imaging studies on the first fully evaluable patient in the trial showed a mixed response, including regression of metastatic tumors in the lungs but evidence of progressive disease at other sites. Evaluation was performed after 3 months and 6 months. After 3 months, despite the extensive prior therapy, the patient's scans noted that, "there has been a clear response in the multiple bilateral pulmonary nodules" indicating that several lung tumors had disappeared or decreased in size. This response was maintained after 6 months of treatment with Bria-IMT<sup>TM</sup>. The liver tumors were stable to slightly increased at 3 months, and then progressed after 6 months.

The lung regressions are especially notable as this patient had previously received many different courses of chemotherapy with a total of 8 different agents. The response in this patient is also highly significant as she shares two HLA matches with Bria-IMT™, lending further support for BriaCell's hypothesis that a heightened anti-tumor response can be elicited by Bria-IMT™ in patients with HLA matches. This supporting data clears the path to the development of Bria-OTS™, the Company's novel approach to a highly personalized immunotherapy, but without the usually associated high costs.'

Additional patients have also shown responses in clinical lesions and also had HLA matches with Bria-IMT<sup>TM</sup>. This information will be detailed in future scientific presentations.

# <u>cGMP Manufacturing of Bria-IMT™ at the University of California, Davis GMP Facility</u>

Bria-IMT<sup>™</sup> has been and will be manufactured under current Good Manufacturing Practice (cGMP), the highest standard of manufacturing prescribed by the FDA. The Company signed a Definitive Agreement with the University of California, Davis Health System ("UC Davis") for cGMP manufacturing of Bria-IMT<sup>™</sup> on June 11, 2015, as a result of positive feedback from the FDA to the Company's response letter dated May 19, 2015. The GMP facility at UC Davis currently formulates Bria-IMT<sup>™</sup> for the patients enrolled in the Company's "combination therapy" Phase I/IIa clinical trial (ClinicalTrials.gov Identifier: NCT03328026).

## cGMP Manufacturing of Bria-IMT™ at KBI Biopharma, Inc.

cGMP-grade Bria-IMT™ is also manufactured at KBI Biopharma, Inc. (The Woodlands, Tx). As outlined in a press release dated September 14, 2017, KBI Biopharma, Inc. is developing a novel formulation of Bria-IMT™ permitting cold-chain (liquid nitrogen-based dry shippers) transport to the clinical sites. The current formulation of Bria-IMT™ is available at the UC Davis GMP Facility (Sacramento, CA) and requires transport at 2-8°C to the clinical sites where it needs to be inoculated within 24 hours after completion of the formulation process.

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### Bria-IMT™ Phase I/IIa Combination clinical trial

Development of Combination Therapy Protocol

In a press release dated Oct 30, 2017 BriaCell announced that the FDA has approved a combination study of Bria-IMT™ with pembrolizumab {Keytruda; manufactured by Merck & Co., Inc. (NYSE: MRK)} or ipilimumab {Yervoy; manufactured by Bristol-Myers Squibb Company (NYSE:BMY)} for patients previously treated with Bria-IMT™ from the ongoing Phase I/IIa Clinical Trial in Advanced Breast Cancer. This combination study allows the patients who did not respond to Bria-IMT™ (monotherapy) treatment to be treated and continue to receive the potential clinical benefits of Bria-IMT™ in combination with either pembrolizumab or ipilimumab. This approach is based on the hypothesis that both pembrolizumab and ipilimumab may improve the anti-tumor activity of Bria-IMT™ in patients with advanced breast cancer. Safety and efficacy data will be evaluated.

BriaCell recently modified the protocol so that new patients can enter directly into the Combination ("Combo") study entitled "A Phase I/IIa Study of the SV-BR-1-GM Regimen in Metastatic or Locally Recurrent Breast Cancer Patients in Combination with Ipilimumab or Pembrolizumab" (ClinicalTrials.gov Identifier: NCT03328026). The Combo study is currently (status: December 14, 2018) open for enrollment at several clinical sites that enrolled patients into the "monotherapy study". Previously, tumor progression on the "monotherapy" study was an inclusion criterion for the Combo study, but FDA has approved the protocol amendment so patients can now directly enter into the Combo study.

### First dosings

As announced in a press release dated October 9, 2018, BriaCell had initiated patient dosing in a Phase I/IIa study of its lead clinical candidate, Bria-IMT™, in combination with pembrolizumab [KEYTRUDA®; manufactured by Merck & Co., Inc. (NYSE: MRK)] or ipilimumab [YERVOY®; manufactured by Bristol-Myers Squibb Company (NYSE: BMY)]. The combination study is listed in ClinicalTrials.gov as NCT03328026. Analysis of blood samples collected in the previous Bria-IMT™ phase I/IIa study (without checkpoint inhibition) showed that circulating tumor-associated cells expressed the immune checkpoint molecule programmed death-ligand 1 (PD-L1). PD-L1 molecules block immune cells from attacking cancer cells. KEYTRUDA® neutralizes the blocking mechanism of PD-L1 while YERVOY® blocks other aspects of immune suppression and as such may also activate the immune system to destroy cancer cells. To date (December 14, 2018), 6 patients have been dosed with Bria-IMT™ in combination with KEYTRUDA without treatment-related serious adverse events.

Rationale for the combination study of Bria-IMT™ with KEYTRUDA® or YERVOY®

Immune checkpoint inhibitors such as pembrolizumab (KEYTRUDA®; anti-PD-1) and ipilimumab (YERVOY®; anti-CTLA-4), designed to overcome immune suppression in cancer patients, have come to the forefront in the fight against cancer with substantial benefits for some patients. Most recently, the significance of immune checkpoint inhibitors was recognized by the Nobel committee by awarding Dr. Tasuku Honjo (PD-1) and Dr. James P. Allison (CTLA-4) the 2018 Nobel Prize in Physiology or Medicine (Scientists behind game-changing cancer immunotherapies win Nobel medicine prize), validating the Company's decision to launch a combination therapy with the immune checkpoint inhibitors.

In 2010, an important pre-clinical study by Dr. Allison's group showed that combination with anti-PD-1 and anti-CTLA-4 antibodies potentiated the tumor-rejection effect of irradiated melanoma cells engineered to produce immune-activating factors.

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Bria-IMT<sup>™</sup>, in essence a breast cancer cell line engineered to produce an immune-activating factor (GM-CSF), has been shown to stimulate T cells, i.e., important cells of the immune system. BriaCell has published these findings in a leading immunology journal in the first half of 2018. Based on the published, proposed mechanism of action of Bria-IMT<sup>™</sup>, the Company envisions that Bria-IMT<sup>™</sup> and immune checkpoint inhibitors can exert additive or synergistic tumor-directed effects. It is important to note that pembrolizumab (KEYTRUDA) and ipilimumab (YERVOY) have not been shown to work on their own in breast cancer but are approved for other indications.

#### Small Molecule Program

On July 24, 2017, the Company entered into a definitive share exchange agreement (the "Share Exchange Agreement") with its wholly-owned subsidiary, BriaCell Therapeutics Corp., and Sapientia Pharmaceuticals, Inc. including all the shareholders of Sapientia. Sapientia, a biotechnology company based in Havertown, PA, is developing novel targeted therapeutics for multiple indications including several cancers and fibrotic diseases.

Pursuant to the terms of the Share Exchange Agreement, BriaCell Therapeutics Corp agreed to acquire from the Sapientia Shareholders all of the issued and outstanding shares in the capital of Sapientia in consideration to the Sapientia Shareholders, pro rata, of an aggregate of 2,500,002 common shares in the capital of BriaCell (the "Transaction"), which were issued on September 5, 2017. As part of the Transaction, BriaCell acquired all rights, including composition of matter patents, and preclinical study data to a novel therapeutic technology platform, known as protein kinase C delta (PKCδ) inhibitors, which represents a unique, highly-targeted approach to treat cancer and to boost the immune system.

On November 13, 2017, BriaCell disclosed the allowance by the US Patent and Trademark Office (USPTO) and also the European Patent Office (EPO) of two patent applications related to protein kinase C delta (PKC $\delta$ ) inhibitor technology, titled "PKC Delta Inhibitors for use as Therapeutics". In a related matter, BriaCell announced the advancement of its small molecule program based on its proprietary PKC $\delta$  inhibitor technology.

#### Conference Presentations

As announced in a press release dated March 1, 2018, Dr. Williams, BriaCell's CEO, presented on March 6, 2018 at the Precision Breast Cancer Conference, a Pharma R&D summit, in Boston, MA. Dr. Williams discussed Bria-IMT<sup>TM</sup>/OTS<sup>TM</sup>, the Company's off-the-shelf personalized approach to cancer.

The positive early clinical data identifying regression in 20 of 20 pulmonary metastases was discussed as part of a major summation lecture at the 35<sup>th</sup> Annual Breast Cancer Conference, March 8-11, 2018 by Dr. George Peoples.

As announced in press releases dated April 10 and 18, 2018, BriaCell was selected for two poster presentations at the Annual Meeting of the American Association for Cancer Research (AACR) held April 14-18, 2018 in Chicago, Illinois.

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One poster, a late-breaking presentation entitled "SV-BR-1-GM, a Whole-Cell Targeted Immunotherapy for Breast Cancer: Preliminary Clinical Data" highlighted the preliminary safety and efficacy of the Company's lead product candidate, Bria-IMT<sup>TM</sup>. Led by Dr. Jarrod P. Holmes of Saint Joseph Heritage Healthcare, Santa Rosa, CA and the clinical teams at Bria-Cell and Cancer Insight, LLC., this poster presentation provided data from the Bria-IMT<sup>TM</sup> Phase I/IIa clinical trial (listed in ClinicalTrials.gov as NCT03066947). The presentation demonstrated that Bria-IMT<sup>TM</sup>, delivered as a monotherapy regimen along with other immune system modulators, generated tumor reduction in some patients. Specifically, the data showed the following:

- The regimen produced clinically relevant regression of metastases (i.e. cancer that has spread to other sites) in patients with advanced Stage IV breast cancer
- Response was rapid and fully developed by 3 months and durable at 6 months
- The responses developed despite previous chemotherapy with multiple different regimens
- The regimen appeared to be safe and well-tolerated
- The tumor reduction responses appeared most pronounced in patients who match with Bria-IMT™ at one or more HLA loci

The other poster, entitled "Targeted immunotherapy with SV-BR-1-GM: Mechanism of action and companion diagnostic development", was led by Markus D. Lacher, PhD, BriaCell's Head of R&D, and provided information regarding the mechanism of action of Bria-IMT™. The data showed the following:

- Tumor regressions were observed, especially in breast cancer patients HLA-matching with Bria-IMT™.
- Anti-SV-BR-1 antibody level changes after Bria-IMT™ treatment suggesting additional paths for tumor attack.
- Interleukin (IL)-8 levels increased in *HLA-DRB3*-matched subjects suggesting a potentially higher-level anti-tumor activity in patients who match Bria-IMT<sup>™</sup> at HLA-DRB3.

As announced in press releases dated May 21 and 29, 2018, BriaCell had an abstract accepted for publication in the proceedings for the American Society of Clinical Oncology (ASCO) national meeting. The abstract summarizes the clinical data on 6 advanced breast cancer patients dosed with Bria-IMT™ in the ongoing Phase I/IIa clinical study (NCT03066947). The clinical data showed that Bria-IMT™ treatment was safe and well-tolerated. Most importantly, tumor volumes were significantly reduced in 2 of 6 advanced breast cancer patients who have failed a number of prior treatments. These findings are important because these 2 patients matched Bria-IMT™ at specific HLA types, providing additional support for the Company's hypothesis for the unique mechanism of action of Bria-IMT™ which sets it apart from similar immunotherapies and provides the logic for further development of BriaDX™, BriaCell's companion diagnostic test. The ASCO abstract be accessed can this http://abstracts.asco.org/214/AbstView\_214\_229215.html (accessed 20 June 2018).

As announced in a press release dated June 13, 2018, BriaCell presented at the 2018 MicroCap Conference on June 21st in Toronto, Canada. Dr. Bill Williams, BriaCell's President and CEO, discussed Bria-IMT<sup>TM</sup>, BriaCell's lead clinical candidate, its potential in treating breast cancer, and its advantages over similar immuno-oncology therapeutics. He also discussed the clinical development plans for Bria-OTS<sup>TM</sup>, the first off-the-shelf personalized immunotherapy in development for advanced breast cancer. Additionally, Dr. Williams discussed the promising clinical data in the ongoing clinical studies of Bria-IMT<sup>TM</sup> in advanced breast cancer. The MicroCap Conference is an exclusive event for investors who specialize in small and microcap stocks. It is an opportunity to be introduced to and speak with management at some of the most attractive small companies, learn from various expert panels, and mingle with other microcap investors.

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Similarly, the Company presented at the MicroCap Conference held Oct. 1-2, 2018, New York, NY, USA, as outlined in a press release on September 21, 2018 announcing that the presentation will summarize the overall Corporate Update on BriaCell's activities and new developments, including Phase I/IIa safety and efficacy data, discovery of tumor shrinkage mechanism, and the Company's upcoming milestones.

As also announced in the September 21, 2018 press release, BriaCell presented a poster at the Fourth CRI-CIMT-EATI-AACR International Cancer Immunotherapy Conference: Translating Science into Survival (Sept. 30 – Oct. 3, 2018, New York, NY, USA), a conference mainly for scientific and medical professionals. The poster described findings related to biological (pharmacodynamic) and clinical responses to treatment with Bria-IMT<sup>TM</sup> in advanced breast cancer patients enrolled in the Company's Phase I/IIa Study of Bria-IMT<sup>TM</sup> in metastatic or locally recurrent breast cancer patients, listed in ClinicalTrials.gov as NCT03066947. Among others, the poster indicated that numbers of a circulating tumor-associated cell type detected in liquid biopsies were reduced in some clinical trial subjects matching with Bria-IMT<sup>TM</sup> after dosing with Bria-IMT<sup>TM</sup>. Such findings are considered key in the context of BriaCell's BriaDX<sup>TM</sup>, a diagnostic test under development to determine which patients are most likely to respond to treatment.

On December 6, 2018, as announced in press releases dated November 19 and 20, and December 6, 2018, a poster was presented at the 2018 San Antonio Breast Cancer Symposium (SABCS) held in San Antonio, TX, USA highlighting data on Bria-IMT<sup>TM</sup> without checkpoint inhibition, demonstrating positive proof-of-concept and an initial assessment of safety and tolerability for Bria-IMT<sup>TM</sup> in combination with pembrolizumab [KEYTRUDA®; manufactured by Merck & Co., Inc. (NYSE: MRK)], a checkpoint inhibitor, for advanced breast cancer, listed in ClinicalTrials.gov as NCT03328026.

The December 6, 2018 press release announced that twenty-three patients had been dosed with Bria-IMT™ in the monotherapy study (not in combination with KEYTRUDA) and that the patients were very heavily pre-treated and had advanced breast cancer with a median of four prior systemic therapy regimens. It further stated that treatment was generally safe and well tolerated with no related grade >3 or unexpected adverse events, that the most common adverse event was expected minor local irritation at the injection sites, that efficacy data showed tumor shrinkage in three patients, all of whom matched Bria-IMT<sup>™</sup> at least at one HLA type (allele), and that one patient, the top respondent, previously received seven chemotherapy regimens and had tumors in the liver, bone and 20 different breast cancer nodules in the lungs. She matched Bria-IMT™ at Class I & II HLA types (alleles). Imaging analysis at three months showed disappearance or reduction of all 20 tumors in the lungs. This response was maintained at six months. Another patient matched Bria-IMT<sup>™</sup> at one HLA type (allele) and had tumor reduction in the skin. A third patient had tumor reduction in the breast. Biological activity was also seen in several patients as evidenced by decreases in circulating cancer-associated cells, potentially also indicating anti-tumor activity of the Bria-IMT™ regimen. This was more frequently seen in patients with HLA matching to Bria-IMT<sup>TM</sup>. In summary, all patients with tumor shrinkage matched with Bria-IMT™ at one or more HLA allele.

Activation of T cells, an important component of the immune system, was measured by delayed-type hypersensitivity (DTH) testing during treatment. Even though 60% of the patients could not mount a DTH response to a common yeast, Bria-IMT $^{\text{TM}}$  treatment elicited a DTH response in 59% of the patients and this was particularly robust in the patients with tumor regression. This suggests that Bria-IMT $^{\text{TM}}$  can elicit a robust immune response.

It was also noted that the vast majority of patients in the study expressed PD-L1 on their circulating cancer-associated cells, supporting the use of Keytruda® in combination with Bria-IMT™. Initial data on the combination of the Bria-IMT™ regimen with KEYTRUDA® suggests the combination is safe and well tolerated. BriaCell is on track to present initial efficacy data on the combination in 1Q19.

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### Corporate Updates

As announced in a press release dated September 26, 2018, BriaCell has achieved proof of concept in the Phase IIa study of its lead clinical candidate, Bria-IMT™, in advanced breast cancer (ClinicalTrials.gov Identifier: NCT03066947). A webcast was held on September 26, 2018, to discuss the results. The following summarizes clinical findings outlined in said press release:

- BriaCell has achieved positive proof of concept in the Phase IIa study of Bria-IMT™ in advanced breast cancer patients
- Data shows promising anti-tumor activity of Bria-IMT™ in heavily pre-treated advanced breast cancer patients
- Impressive Phase IIa efficacy data is similar or superior to those of other approved breast cancer drugs of similar clinical-stage of development
- Outstanding safety and tolerability profile for Bria-IMT™
- Data confirms "HLA Matching Hypothesis" and supports BriaCell's strategy for the development of Bria-OTS™
- BriaCell has initiated a combination study assessing Bria-IMT™ in patients with immune checkpoint inhibition.

The press release further noted that to date [Sept. 26, 2018], 31 advanced stage breast cancer patients had been enrolled in the Phase IIa Bria-IMT™ monotherapy study and that the Phase IIa confirmatory mechanism of action and proof of concept work was based on the first 20 patients, with assessment of the remaining 11 patients in progress. Given the conclusive findings on the first 20 patients, enrollment for this monotherapy study is now closed, while enrollment for the combination study is open.

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For the Three Month Period Ended October 31, 2018

# 4. SELECTED FINANCIAL INFORMATION

The following financial data prepared in accordance with IFRS in Canadian dollars is presented for the three-month period ended October 31, 2018 and 2017.

	Three months ended October 31		
	2018	2017	
Expenses:			
Research costs	993,201	467,504	
General and administartion costs	291,028	177,830	
Share-based compensation	1,686		
Total Expenses	1,285,915	645,334	
Operating Loss	(1,285,915)	(645,334)	
Interest income	4,314	6,045	
Interest expense	(13,299)	-	
Change in fair value of convertible debt	247,373	-	
Foreign exchange loss		(1,715)	
	238,388	4,330	
Loss For The Period	(1,047,527)	(641,004)	
Items That Will Subsequently Be Reclassified To Profit Or Loss			
Foreign currency translation adjustment	6,040	(34,146)	
	6,040	(34,146)	
Comprehensive Loss for the Period	(1,041,487)	(675,150)	
Basic and Fully Diluted Loss Per Share	\$ (0.01)	\$ (0.01)	
Weighted Average Number Of Shares Outstanding	160,363,484	111,087,721	

# <u>Three-month period ended October 31, 2018, compared to the three-month period ended October 31, 2017</u>

## Research Costs

For the three-month period ended October 31, 2018, research costs amounted to \$993,201 as compared to \$467,504 for the three-month period ended October 31, 2017. The increase in research costs is as a result of supporting the Company's ongoing Phase I/IIa clinical trial and relates primarily to increased clinical trial expenses, including the development of new BriaVax<sup>™</sup> cell banks. BriaCell also has contracted with a second supplier of BriaVax<sup>™</sup> and there is ongoing formulation work to develop a more user-friendly formulation that does not require culturing cells and same day irradiation. Work also has begun on the development of second generation BriaVax<sup>™</sup> and BriaCell has submitted five grant

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

applications, applying for non-dilutive funding to support our research efforts, using our grant consultant, the FreeMind Group.

### General and Administrative Expenses

For the three-month period ended October 31, 2018, general and administrative expenses amounted to \$291,028 as compared to \$177,830 for the three-month period ended October 31, 2017. The increase is primarily due to an increase in Shareholder communication costs incurred in the three-month period ended October 31, 2018 as compared to 2017 and is in line with the company's increased research activities and increase investor relations activities.

### **Share-based Compensation**

For the three-month period ended October 31, 2018, share based compensation of \$1,686 as compared to nil for the three-month period ended October 31, 2017.

#### Interest Income

For the three-month period ended October 31, 2018, interest income amounted to \$4,314 as compared to \$6,045 for the three-month period ended October 31, 2017. Interest income earned during each quarter is a function of the amount of funds held in interest bearing accounts.

### Interest expense

For the year ended July 31, 2018, interest expense amounted to \$13,299 as compared to \$nil for the year ended October 31, 2017. Interest expense was incurred as a result of the issuance of interest bearing convertible notes in March 2018.

# Foreign Exchange Loss

For the three-month period ended October 31, 2018, the foreign exchange of nil as compared to a loss of \$1,715 for the three-month period ended October 31, 2017. The Company is exposed to financial risk related to the fluctuation of foreign exchange rates. The Company operates in the United States and Canada, most of its monetary assets are held in Canadian dollars and most of its expenditures are made in US dollars. The Company has not hedged its exposure to currency fluctuations.

#### Loss for the period

The Company reported a loss for the three-month period ended October 31, 2018 of \$1,047,527 as compared to a loss of \$641,004 for the three-month period ended October 31, 2017. The primary reason for increase in the loss in 2018 is due to the increased research activities during the current period.

#### Comprehensive loss for the period

The Company reported a comprehensive loss for the three-month period ended October 31, 2018 of \$1,041,487 as compared to a comprehensive loss of \$675,150 for the three-month period ended October 31, 2017. The primary reason for increase in the loss in 2018 is due to the increased research activities during the period. The difference between net loss and comprehensive loss results from:

The difference between net loss and comprehensive loss results from Foreign currency translation adjustment that arises upon the translation of the accounting records of BTC who's functional currency is the US dollar into Canadian dollars for financial statement presentation purposes.

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For the Three Month Period Ended October 31, 2018

# 5. SUMMARY OF QUARTERLY RESULTS

The following is a summary of the Company's quarterly results for the last eight quarters ended October 2018.

	QUARTER ENDED						
		October 31 2018		July 31 2018	April 30 2018		January 31 2018
Total revenue	\$	-	\$	-	\$ -	\$	-
Net loss before income taxes	\$	(1,047,527)	\$	(2,143,945)	\$ (1,656,416)	\$	(971,298)
Net loss for the period	\$	(1,047,527)	\$	(2,143,945)	\$ (1,656,416)	\$	(971,298)
Basic loss per share	\$	(0.01)	\$	(0.02)	\$ (0.01)	\$	(0.006)

	QUARTER ENDED							
		October 31		July 31		April 30		January 31
	-	2017	-	2017	-	2017		2017
Total revenue	\$	-	\$	-	\$	-	\$	-
Net loss before income taxes	\$	(641,004)	\$	(1,188,561)	\$	(1,178,408)	\$	(414,534)
Net loss for the period	\$	(641,004)	\$	(1,188,561)	\$	(1,178,408)	\$	(414,534)
Basic loss per share	\$	(0.01)	\$	(0.01)	\$	(0.01)	\$	(0.001)

Net loss per quarter is primarily a function of the research and operational activity during that quarter. There is no seasonal trend. Commencing from the quarter ended April 30, 2017 through to the current quarter ended October 31, 2018 the company's quarterly loss increased significantly due to the costs incurred the ongoing Phase I/IIa clinical trial.

# 6. LIQUIDITY

The Company has financed its operations to date primarily through the issuance of its common shares. The Company continues to seek capital through various means including the issuance of equity and/or debt.

The financial statements have been prepared on a going concern basis which assumes that the Company will be able to realize its assets and discharge its liabilities in the normal course of business for the foreseeable future. The continuing operations of the Company are dependent upon its ability to continue to raise adequate financing and to commence profitable operations in the future.

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

As at October 31, 2018, the Company has total assets of \$1,845,369 (July 31, 2018 - \$2,977,140) and negative working capital of \$53,306 (July 31, 2018 – positive \$700,350).

It is management's opinion that the Company will require additional funding, either through debt or equity issuances, in order to maintain its research and developmental activities. These uncertainties may cast significant doubt on the Company's ability to continue as a going concern.

Three-month period ended October 31, 2018, compared to the three-month period ended October 31, 2017

During the three-month period ended October 31, 2018, the Company's overall position of cash and cash equivalents decreased by \$697,757. This decrease in cash can be attributed to the following:

The Company's net cash used in operating activities during the three-month period ended October 31, 2018 was \$1,437,757 as compared to \$1,327,702 for the three-month period ended October 31, 2017. This increase is in line with the increase in our operating loss for 2018 as compared to the same period in 2017.

Cash provided from investing activities during the three-month period ended October 31, 2018 was \$600,000 as compared to cash used to investment activities of \$100,149 for the three-month period ended October 31, 2017. The cash provided in 2018 was mostly due to the release of short-term investments.

Cash provided by financing activities for the three-month period ended October 31, 2018 was \$140,000 as compared to \$631,786 for the three-month period ended October 31, 2017. Cash provided in 2018 was from the exercise of warrants and the cash provided in 2017 resulted from the August 2017 private placements.

#### 7. CAPITAL RESOURCES

At October 31, 2018, the Company's capital resources consist primarily of cash and short term investments.

#### 8. OFF BALANCE SHEET ARRANGEMENTS

The Company has not entered into any off-Balance Sheet arrangements.

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

### 9. TRANSACTIONS BETWEEN RELATED PARTIES

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making operating and financial decisions. This would include the Company's senior management, who are considered to be key management personnel by the Company.

Parties are also related if they are subject to common control or significant influence. Related parties may be individuals or corporate entities. A transaction is considered to be a related party transaction when there is a transfer of resources or obligations between related parties.

As at October 31, 2018, included in accounts payable and accrued liabilities are amounts owing to a company controlled by an officer in the amount of 6,000 (October 31, 2017 - 3,500) for accounting fees; amounts owing to two companies each controlled by an individual director of 7,000 (October 31, 2017 - 31,500) for consulting fees and amounts owing to directors of 7,544 (October 31, 2017 - 1,239).

During the three months ended October 31, 2018 and 2017, the Company incurred the following expenses (or recoveries) by key management personnel or companies controlled by these individuals:

	Three months ended October 31		
	2018	2017	
Paid or accrued professional fees to a company controlled by an officer of the Company	15,200	10,500	
Paid or accrued consulting fees to Companies controlled by individual directors.	33,000	31,500	
Paid or accrued wages and consulting fees to directors	64,950	67,553	

- a) Paid or accrued consulting to Ninety-six Capital, a company controlled by Gadi Levin, the Company's CFO.
- b) Paid or accrued consulting to Ameretat Investment Ltd, a company controlled by Saeid Babaei, a director and KJN Management Ltd, a company controlled by Rahoul Sharan
- c) Paid or accrued wages to directors: Dr. Charles Wiseman, Dr. William V. Williams and Mr, Martin Schmieg.

These transactions were in the normal course of operations and were measured at the exchange value which represented the amount of consideration established and agreed to by the related parties.

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

## 10. FINANCIAL INSTRUMENTS AND FINANCIAL RISK EXPOSURES

The Company's financial instruments consist of cash, short term investments, amounts receivable, investments and accounts payable and accrued liabilities. Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest or credit risks arising from these financial instruments. The fair value of these financial instruments approximates their carrying values, unless otherwise noted.

Management understands that the Company is exposed to financial risk arising from fluctuations in foreign exchange rates and the degree of volatility of these rates as its research operations are located in the United States., and the Company's functional and presentation currency is the Canadian dollar. The Company does not use derivative instruments to reduce its exposure to foreign currency risk.

The Company is exposed in varying degrees to a variety of financial instrument related risks. The Board of Directors approves and monitors the risk management process. The overall objectives of the Board are to set policies that seek to reduce risk as far as possible without unduly affecting the Company's competitiveness and flexibility.

The type of risk exposure and the way in which such exposure is managed is as follows:

#### a) Credit risk

The Company has no significant concentration of credit risk arising from operations. Management believes that the credit risk concentration with respect to financial instruments is remote.

### b) Liquidity Risk

The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet liabilities as they come due. As at October 31, 2018, the Company had a negative working capital balance of \$53,306 (July 31, 2018 - \$700,350). As a result, the Company currently has little exposure to liquidity risk. However, as described in Note 1, the Company has not yet achieved profitable operations and expects to incur further losses in the development of its products; these factors cast significant doubt about the Company's ability to continue as a going concern.

# c) Market Risk

#### i) Interest rate risk

The Company has cash and short term investments and no interest-bearing debt. The Company's current policy is to invest excess cash in investment-grade short-term deposit certificates issued by its banking institutions. The Company periodically monitors the investments it makes and is satisfied with the credit ratings of its banks.

# ii) Foreign currency risk

The Company is exposed to foreign exchange risk as its research operations are conducted primarily in the United States.

# c) Fair Values

The carrying values of short term investments, amounts receivable, and accounts payable and accrued liabilities approximate their fair values due to their short terms to maturity.

The cash, short term investments and investments are valued using quoted market prices in active markets.

Management Discussion and Analysis For the Three Month Period Ended October 31, 2018

## 11. CRITICAL ESTIMATES AND JUDGEMENTS

The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The financial statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the financial statements, and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and also in future periods when the revision affects both current and future periods.

The critical judgments and significant estimates in applying accounting policies that have the most significant effect on the amounts recognized in the consolidated financial statements are:

- The series of loans made to the subsidiary company are considered part of the parent company's net investment in a foreign operation as the Company does not plan to settle these balances in the foreseeable future. As a result of this assessment, the unrealized foreign exchange gains and losses on the intercompany loans are recorded through comprehensive loss. If the Company determined that settlement of these amounts was planned or likely in the foreseeable future, the resultant foreign exchange gains and losses would be recorded through profit or loss.
- The determination that the unrealized decrease in the fair value of available for sale investments is other than temporary.
- The fair value of the share consideration deemed issued to acquire BriaCell.

## 12. NEW ACCOUNTING POLICIES ADOPTED

During the three month period ended October 31, 2018, no new accounting policies were adopted.

### 13. ACCOUNTING STANDARDS ISSUED BUT NOT YET EFFECTIVE

Certain pronouncements were issued by the IASB or the IFRIC that are mandatory for future accounting periods. Many are not applicable to or do not have a significant impact on BriaCell and have been excluded from the list below. The following have not yet been adopted and are being evaluated to determine their impact on BriaCell.

(i) IFRS 9 – Financial instruments ("IFRS 9") was issued by the IASB its final form in July 2014 and will replace IAS 39 Financial Instruments: Recognition and Measurement ("IAS 39"). IFRS 9 uses a single approach to determine whether a financial asset is measured at amortized cost or fair value, replacing the multiple rules in IAS 39. The approach in IFRS 9 is based on how an entity manages its financial instruments in the context of its business model and the contractual cash flow characteristics of the financial assets. Most of the requirements in IAS 39 for classification and measurement of financial liabilities were carried forward unchanged to IFRS 9. The new standard also requires a single impairment method to be used, replacing the multiple impairment methods in IAS39. The standard is effective for annual periods beginning on or after January 1, 2018. Management assesses that the adoption of IFRS 9 will not have a significant impact to the consolidated financial statements.

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- (ii) IFRS 15 Revenue from contracts with customers ("IFRS 15") proposes to replace IAS 18 Revenue, IAS 11 Construction contracts and some revenue-related interpretations. The standard contains a single model that applies to contracts with customers and two approaches to recognizing revenue: at a point in time or over time. The model features a contract-based five step analysis of transaction to determine whether, how much and when revenue is recognized. New estimates and judgmental thresholds have been introduced, which may affect the amount and/or timing of revenue recognized. IFRS 15 is effective for annual periods beginning on or after January 1, 2018. Earlier adoption is permitted. The Company has determined there will not be a significant impact to the consolidated financial statements as a result of the adoption of this standard.
- (iii) IFRS 16 Leases ("IFRS 16") replaces IAS 17, Leases ("IAS 17"). The new model requires the recognition of almost all lease contracts on a lessee's statement of financial position as a lease liability reflecting future lease payments and a 'right-of-use asset' with exceptions for certain short-term leases and leases of low-value assets. In addition, the lease payments are required to be presented on the statement of cash flow within operating and financing activities for the interest and principal portions, respectively. IFRS 16 is effective for annual periods beginning on or after January 1, 2019, with early adoption permitted if IFRS 15, Revenue from Contracts with Customers, is also applied. The Company has yet to evaluate the impact of this new standard.

The Company currently intends to adopt the standard on its effective date and has not yet determined its impact on the consolidated financial statements.

(iv) IFRS 17 – Insurance Contract ("IFRS 17") was issued by the IASB in May 2017, which replaces IFRS 4 Insurance Contracts. IFRS 17 requires entities to measure insurance contract liabilities at their current fulfillment values using one of three measurement models, depending on the nature of the contract. IFRS 17 is effective for annual periods beginning on or after January 1, 2021. IFRS 17 will affect how we account for our insurance contracts and how we report our financial performance in our consolidated statement of operations. The Company has yet to evaluate the impact of this new standard.

#### 14. COMMITMENTS

Office Leases

The Company's lease arrangement for office space in Berkeley, California end in August 2019 and the annual lease commitment is approximately US\$50,000 plus common area maintenance charges.

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For the Three Month Period Ended October 31, 2018

## 15. OTHER INFORMATION

The following details the common shares, warrants, compensation warrants, and stock options, warrants outstanding as of the date of this MD&A.

#### **Common Shares**

	Number of Shares
Authorized: Unlimited common shares, without par value	
Issued as at October 31, 2018	161,327,970

#### **Share Purchase Warrants**

Number of Warrants	Exercisable Exercise At Price 31-Jul-18		Expiry Date
3,421,053	\$ 0.30	3,421,053	April 26, 2021
8,500,000	\$ 0.35	8,500,000	August 19, 2019
2,806,041	\$ 0.35	2,806,041	March 9, 2019
1,021,500	\$ 0.20	1,021,500	December 21, 2019
42,322,322	\$ 0.14	42,322,322	March 27, 2021
2,499,645	\$ 0.14	2,499,645	July 2021
60,570,561		60,570,561	-

## **Compensation Warrants**

Number Of Compensation Warrants	Exercise Price	Exercisable At July 31, 2017	Expiry Date
273,685	0.30	273,685	April 26, 2021 (i)
139,000	0.20	139,000	April 29, 201 (ii)
595,000	0.20	595,000	August 19, 2019 (iii)
1,007,685		1,007,685	

- i) Each compensation warrant can be exercised at \$0.30 into one unit of BriaCell comprising one common share and one share purchase warrant. Each resultant share purchase warrant acquired can be exercised into an additional common share of BriaCell at \$0.35 if exercised by April 26, 2021.
- ii) Each compensation warrant can be exercised at \$0.20 into one unit of BriaCell comprising one common share and one share purchase warrant. Each resultant share purchase warrant acquired can be exercised into an additional common share of BriaCell an exercise price of \$0.30 through to August 19, 2019 and \$0.35 for the 24 months thereafter.
- iii) Each compensation warrant can be exercised at \$0.14 into one common share of BriaCell for a period of 36 months.

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Number			Exercisable At	
Of	Ex	ercise	October 31,	Expiry
Options	Price		2018	Date
950,000	\$	0.255	950,000	November 4, 2025
575,000	\$	0.255	418,750	November 4, 2020
150,000	\$	0.210	112,500	March 22, 2020
500,000	\$	0.255	500,000	November 4, 2018
632,000	\$	0.250	632,000	November 1, 2019
250,000	\$	0.200	312,500	February 14, 2020
50,000	\$	0.210	62,500	March 20, 2020
3,400,000	\$	0.150	3,400,000	Mar 1, 2021
500,000	\$	0.200	375,000	March 10, 2022
2,015,600	\$	0.140	1,511,700	May 1, 2021
250,000	\$	0.140	125,000	July 1, 2023
	_			
9,272,600	_		8,399,950	

#### **Shares Held in Escrow**

The escrow agreement relating to the reverse takeover transaction provided for 54,282,952 shares to be held under an escrow agreement, Shares will be released from escrow equal to 10% of the initial shares subject to the agreement upon completion of the initial public offering or purchase agreement and listing on the Canadian Securities Exchange, the remaining shares will be released in 6 equal tranches (15%) every nine-months. On December 1, 2014, the Company received final approval of its change of business and trading of the Company's shares under the new name and ticker symbol commenced on December 3, 2014.

As of October 31, 2018, all the 54,282,952 (October 31, 2017 - 39,329,389) shares have been released and the number of shares remain in escrow is nil (October 31, 2017 - 14,953,563).

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## 16. RISKS AND UNCERTAINTIES

## **History of Operating Losses**

BriaCell is a development stage corporation that to date has not recorded any revenues from the sale of diagnostic or therapeutic products. Since incorporation, BriaCell has accumulated net losses and expects such losses to continue as it commences product and pre-clinical development and eventually enters into license agreements for its technology. Management expects to continue to incur substantial operating losses unless and until such time as product sales generate sufficient revenues to fund continuing operations. BriaCell has neither a history of earnings nor has it paid any dividends and it is unlikely to pay dividends or enjoy earnings in the immediate or foreseeable future.

## **Early Stage Development**

The Company expects to spend a significant amount of capital to fund research and development. As a result, the Company expects that its operating expenses will increase significantly and, consequently, it will need to generate significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it will be profitable. There can be no assurances that the Intellectual Property of BriaCell, or other technologies it may acquire, will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed. The Company will be undertaking additional laboratory studies or trials with respect to the Intellectual Property of BriaCell, and there can be no assurance that the results from such studies or trials will result in a commercially viable product or will not identify unwanted side effects.

# **Ability to Manage Growth**

Anticipated growth in all areas of BriaCell's business is expected to continue to place, a significant strain on its managerial, operational and technical resources. The Company expects operating expenses and staffing levels to increase in the future. To manage such growth, the Company must expand its operational and technical capabilities and manage its employee base while effectively administering multiple relationships with various third parties. There can be no assurance that the Company will be able to manage its expanding operations effectively. Any failure to implement cohesive management and operating systems, to add resources on a cost-effective basis or to properly manage the Company's expansion could have a material adverse effect on its business and results of operations.

# **Unproven Market**

The Company believes that the anticipated market for its potential products and technologies if successfully developed will continue to exist and expand. These assumptions may prove to be incorrect for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.

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### Manufacturing, Pharmaceutical Development and Marketing Capability

The Company does not expect to have any in-house manufacturing, pharmaceutical development or marketing capability. To be successful, a product must be manufactured and packaged in commercial quantities in compliance with regulatory requirements and in reasonable time frames and at accepted costs. The Company intends to contract with third parties to develop its products. No assurance can be given that the Company or its suppliers will be able to meet the supply requirements in respect of the product development or commercial sales.

Production of therapeutic products may require raw materials for which the sources and amount of supply are limited, or may be hindered by quality or scheduling issues in respect of the third party suppliers over which the Company has limited control. An inability to obtain adequate supplies of raw materials could significantly delay the development, regulatory approval and marketing of a product. The Company has limited in-house personnel to internally manage all aspects of product development, including the management of multi-center clinical trials. The Resulting Issuer is significantly reliant on third party consultants and contractors to provide the requisite advice and management. There can be no assurance that the clinical trials and product development will not encounter delays which could adversely affect prospects for the Company's success.

To be successful, an approved product must also be successfully marketed. The market for the Company's product being developed by the Company may be large and will require substantial sales and marketing capability. At the present time, the Company has no any internal capability to market pharmaceutical products. The Company intends to enter into one or more strategic partnerships or collaborative arrangements with pharmaceutical companies or other companies with marketing and distribution expertise to address this need. If necessary, the Company will establish arrangements with various partners for geographical areas. There can be no assurance that the Company can market, or can enter into a satisfactory arrangement with a third party to market a product in a manner that would assure its acceptance in the market place. However, if a satisfactory arrangement with a third party to market and/or distribute a product is obtained; the Company will be dependent on the corporate collaborator(s) who may not devote sufficient time, resources and attention to the Company's programs, which may hinder efforts to market the products.

Should the Company not establish marketing and distribution strategic partnerships and collaborative arrangements on acceptable terms, and undertake some or all of those functions, the Company will require significant additional human and financial resources and expertise to undertake these activities, the availability of which is not guaranteed.

The Company will rely on third parties for the timely supply of raw materials, equipment, contract manufacturing, and formulation or packaging services. Although the Company intends to manage these third party relationships to ensure continuity and quality, some events beyond the Company's control could result in complete or partial failure of these goods and services. Any such failure could have a material adverse effect on the financial conditions and result of operation of the Company

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### Pre-Clinical Studies and Initial Clinical Trials are not Necessarily Predictive of Future Results

Pre-clinical tests and Phase I/II clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical and early clinical trials does not ensure that later large-scale efficacy trials will be successful nor does it predict final results. Favorable results in early trials may not be repeated in later trials.

A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials, even after positive results in earlier trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. Any pre-clinical data and the clinical results obtained for BriaCell's technology may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in the commercial setting, and also may not predict the ability of our products to achieve their intended goals, or to do so safely.

# **Raw Materials and Product Supply**

Raw materials and supplies are generally available in quantities to meet the needs of the Company's business. The Company will be dependent on third-party manufacturers for the pharmaceutical products that it markets. An inability to obtain raw materials or product supply could have a material adverse impact on the Company's business, financial condition and results of operations.

### Liquidity and Need for Additional Capital and Access to Capital Markets

The Company anticipates that additional capital will be required to complete its current research and development programs. It is anticipated that future research, additional pre-clinical and toxicology studies and manufacturing initiatives, including that to prepare for market approval and successful product market launch will require additional funds. Further financing may dilute the current holdings of Shareholders and may thereby result in a loss for the shareholders. There can be no assurance that the Company will be able to obtain adequate financing, or financing on terms that are reasonable or acceptable for these or other purposes, or to fulfill the Company's obligations under various license agreements. Failure to obtain such additional financing could result in delay or indefinite postponement of further research and development of the Company's technologies with the possible loss of license rights to these technologies.

Although the Company's common shares are listed for trading on the TSXV, there can be no assurance that a liquid market will exist which may have an adverse effect on the market price of the Company's common shares.

### Competition

The market for BriaCell's technology is highly competitive. The Company will compete with other research teams who are also examining potential therapeutics with regards to autoimmune diseases and disorders. Many of its competitors have greater financial and operational resources and more experience in research and development than the Company. These and other companies may have developed or could in the future develop new technologies that compete with the BriaCell's technologies or even render its technologies obsolete. Competition in BriaCell's markets is primarily driven by timing of technological introductions; ability to develop, maintain and protect proprietary products and technologies; and expertise of research and development team.

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### **Dependence on Third Parties**

Due to the complexity of the process of developing pharmaceutical products which includes immunotherapeutic products and therapeutic vaccines, the Company's business may depend on arrangements with pharmaceutical and biotechnology companies, corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, technology rights, manufacturing, marketing and commercialization of its products. Such agreements could obligate the Company to diligently bring potential products to market, make milestone payments and royalties that, in some instances, could be substantial, and incur the costs of filing and prosecuting patent applications. There can be no assurance that the Company will be able to establish or maintain collaborations that are important to its business on favourable terms, or at all.

A number of risks arise from the Company's potential dependence on collaborative agreements with third parties. Product development and commercialization efforts could be adversely affected if any collaborative partner terminates or suspends its agreement with the Company, causes delays, fails to on a timely basis develop or manufacture in adequate quantities a substance needed in order to conduct clinical trials, fails to adequately perform clinical trials, determines not to develop, manufacture or commercialize a product to which it has rights, or otherwise fails to meet its contractual obligations. The Company's collaborative partners could pursue other technologies or develop alternative products that could compete with the products the Company is developing.

The Company has signed Non-Disclosure Agreements ("NDA") with many different third as is customary in the industry. There is no guarantee that, despite the terms of the NDA which bind third parties, the Company will ultimately be able to prevent from such third parties from breaching their obligations under the NDA. Use of the Company's confidential information in an unauthorized manner is likely to negatively affect the Company.

### **Intellectual Property**

BriaCell's success depends to a significant degree upon its ability to develop, maintain and protect proprietary products and technologies. BriaCell files patent applications in the United States as part of its strategy to protect its Intellectual Property. However, patents provide only limited protection of BriaCell's Intellectual Property. The assertion of patent protection involves complex legal and factual determinations and is therefore uncertain and expensive. BriaCell cannot provide assurances that patents will be granted with respect to any of its pending patent applications, that the scope of any of its patents will be sufficiently broad to offer meaningful protection, or that it will develop additional proprietary technologies that are patentable. BriaCell's current patents could be successfully challenged, invalidated or circumvented. This could result in BriaCell's patent rights failing to create an effective competitive barrier. Losing a significant patent or failing to get a patent to issue from a pending patent application that BriaCell considers significant could have a material adverse effect on the Company's business. The laws governing the scope of patent coverage in various countries continue to evolve. The laws of some foreign countries may not protect BriaCell's intellectual property rights to the same extent as the laws of United States. BriaCell holds patents only in selected countries. Therefore, third parties may be able to replicate BriaCell technologies covered by BriaCell's patents in countries in which it does not have patent protection.

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# Litigation to Protect the Company's Intellectual Property

The Company's future success and competitive position depends in part upon its ability to maintain its Intellectual Property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications. Even if such patents are issued, there can be no assurance that any patents issued or licensed to the Company will not be challenged. The Company's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of the Company's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Even if such claims are found to be invalid, the Company's involvement in intellectual property litigation could have a material adverse effect on its ability to distribute any products that are the subject of such litigation. In addition, the Company's involvement in intellectual property litigation could result in significant expense, which could materially adversely affect the use responsibilities, whether or not such litigation is resolved in the Company's favour.

# **Legal Proceedings**

In the course of the Company's business, the Company may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against the Company asserting that it has misappropriated their technologies and had improperly incorporated such technologies into the Company's products.

Due to these factors, there remains a constant risk of intellectual property litigation affecting the Company's business. In the future, the Company may be made a party to litigation involving intellectual property matters and such actions, if determined adversely, could have a material adverse effect on the Company.

### **Dependence upon Management**

Although the Company is expected to have experienced senior management and personnel, the Company will be substantially dependent upon the services of a few key personnel, particularly Dr. Charles Wiseman and Dr. Williams V. Williams and the professionals for the successful operation of its business. Phase I of the Company's research and development is planned to be completed by qualified professionals and is expected to concentrate on engaging the pharmaceutical companies for the licensing of the new vaccine candidates. The loss of the services of any of these personnel could have a material adverse effect on the business of the Company. The Company may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among high technology enterprises, including biotechnology, and healthcare companies, universities and non-profit research institutions. If it loses any of these persons, or is unable to attract and retain qualified personnel, its business, financial condition and results of operations may be materially and adversely affected.

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### Other legislation or regulatory proposals may affect the Company's revenues and profitability.

Existing and proposed changes in the laws and regulations affecting public companies may cause the Company to incur increased costs as the Company evaluates the implications of new rules and responds to new requirements. Failure to comply with new rules and regulations could result in enforcement actions or the assessment of other penalties. New laws and regulations could make it more difficult to obtain certain types of insurance, including director's and officer's liability insurance, and the Company may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage, to the extent that such coverage remains available.

The impact of these events could also make it more difficult for the Company to attract and retain qualified persons to serve on the Company's board of directors, or as executive officers. The Company may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause the Company's general and administrative costs to increase beyond what the Company currently has planned. Although the Company evaluates and monitors developments with respect to new rules and laws, the Company cannot predict or estimate the amount of the additional costs the Company may incur or the timing of such costs with respect to such evaluations and/or compliance and cannot provide assurances that such additional costs will render the Company compliant with such new rules and laws.

# If the Company experiences a data security breach and confidential information is disclosed, the Company may be subject to penalties and experience negative publicity

The Company and its customers could suffer harm if personal and health information were accessed by third parties due to a system security failure. The collection of data requires the Company to receive and store a large amount of personally identifiable data. Recently, data security breaches suffered by well-known companies and institutions have attracted a substantial amount of media attention, prompting legislative proposals addressing data privacy and security. The Company may become exposed to potential liabilities with respect to the data that it collects, manages and processes, and may incur legal costs if information security policies and procedures are not effective or if the Company is required to defend its methods of collection, processing and storage of personal data. Future investigations, lawsuits or adverse publicity relating to its methods of handling such information could have a material adverse effect on the Company's business, financial condition and results of operations due to the costs and negative market reaction relating to such developments.

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## 17. MD&A PREPARATION

This MD&A was prepared as of December 28, 2018. This MD&A should be read in conjunction with audited consolidated financial statements for the year ended July 31, 2018. This MD&A is intended to assist the reader's understanding of **BriaCell Therapeutics Corp**. and its' operations, business, strategies, performance and future outlook from the perspective of management. The documents mentioned above, as well as news releases and other important information may be viewed through the SEDAR website at www.sedar.com.

## Managements Responsibility for Financial Statements

The information provided in this report, is the responsibility of management. During the preparation of financial statements, estimates are sometimes necessary to make a determination of future values for certain assets or liabilities. Management believes such estimates have been based on careful judgments and have been properly reflected in the accompanying financial statements.

Management maintains a system of internal controls to provide reasonable assurance that the company's assets are safeguarded and to facilitate the preparation of relevant and timely information.

BriaCell's of Directors follows recommended corporate governance guidelines for public companies to ensure transparency and accountability to shareholders. The Board's Audit Committee meets with management quarterly to review the financial statement results, including the MD&A, and to discuss other financial, operating and internal control matters. The Audit Committee receives a report from the independent auditors annually, and is free to meet with them throughout the year.