



BriaCell Therapeutics Corp.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED OCTOBER 31, 2022

DECEMBER 14, 2022

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Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

References to the “Company,” “our,” “us” or “we” refer to BriaCell Therapeutics Corp. The following discussion and analysis of the Company’s financial condition and results of operations should be read in conjunction with the unaudited condensed consolidated financial statements and the notes thereto contained elsewhere in this report. Certain information contained in the discussion and analysis set forth below includes forward-looking statements that involve risks and uncertainties.

Introduction

This Management’s Discussion and Analysis (“MD&A”) should be read together with other information, including our unaudited condensed interim consolidated financial statements and the related notes to those statements included in Part I, Item 1 of this Quarterly Report (the “Condensed Consolidated Financial Statements”), our consolidated financial statements appearing in our Annual Report on Form 10-K for the year ended July 31, 2022 (the “Annual Report”) and Part I, Item 1A, Risk Factors, of the Annual Report. This MD&A provides additional information on our business, recent developments, financial condition, cash flows and results of operations, and is organized as follows:

- *Part 1 - Business Overview.* This section provides a general description of our business, which we believe is important in understanding the results of our operations, financial condition, and potential future trends.
- *Part 2 - Results of Operations.* This section provides an analysis of our results of operations for the first quarter of fiscal 2023 in comparison to the first quarter of fiscal 2022.
- *Part 3 - Financial Liquidity and Capital Resources.* This section provides an analysis of our cash flows and outstanding debt and commitments. Included in this analysis is a discussion of the amount of financial capacity available to fund our ongoing operations and future commitments.

We prepare and report our unaudited Condensed Consolidated Financial Statements in accordance with U.S. GAAP. Our unaudited Condensed Consolidated Financial Statements, and the financial information contained herein, are reported in U.S Dollars.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. We have based these forward-looking statements on our current expectations and projections about future events. These forward-looking statements are subject to known and unknown risks, uncertainties and assumptions about us that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may,” “should,” “could,” “would,” “expect,” “plan,” “anticipate,” “believe,” “estimate,” “continue,” or the negative of such terms or other similar expressions. Factors that might cause or contribute to such a discrepancy include, but are not limited to, those described in our other SEC filings.

Overview

BriaCell (the “**Company**”) is an immuno-oncology biotechnology company with a strong focus on cancer immunotherapy. Immunotherapies have come to the forefront in the fight against cancer since they harness the body’s own immune system to recognize and destroy cancer cells. BriaCell owns the U.S. patent to SV-BR-1-GM (“**Bria-IMT™**”), 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 our targeted immunotherapy program by prioritizing a Phase I/IIa clinical trial with Bria-IMT™ in combination with an immune checkpoint inhibitor and a companion diagnostic test, BriaDx™, to identify patients most likely to benefit from Bria-IMT™. The Bria-IMT™ regimen was evaluated in four patients in a prior study in 2004-2006 by Dr. Charles Wiseman, the scientific founder, former member of the board of directors of the Company (the “**Board**”) and principal scientific advisor. Encouraging results were obtained, especially in a patient who matched Bria-IMT™ at HLA-DR alleles and had a grade II tumor. In 2017-2018 BriaCell evaluated 23 patients with advanced breast cancer with the Bria-IMT™ regimen and obtained confirmation of the ability of the Bria-IMT™ regimen to induce regression of metastatic breast cancer in patients who match Bria-IMT™ at least at one HLA allele and/or if they had grade I or grade II tumors. A combination study with the immune checkpoint inhibitor pembrolizumab (KEYTRUDA®) was initiated and the first patient dosing in the “combination therapy” clinical trial occurred in September 2018. BriaCell purchased the KEYTRUDA® for this study as BriaCell does not have an agreement with Merck & Co., Inc. for the supply of KEYTRUDA®. Eleven patients were dosed in the combination therapy trial with Bria-IMT™ and the immune checkpoint inhibitor KEYTRUDA® and subsequently dosing with this combination was discontinued. The study was modified under an amended protocol which evaluates the combination of the Bria-IMT™ regimen with Incyte Corporation experimental drugs retifanlimab (anti-PD-1 antibody similar to pembrolizumab). The study is ongoing.

It is estimated by the National Cancer Institute that in 2022, approximately 287,500 women will be diagnosed with breast cancer in the United States. That means that every two minutes an American woman is diagnosed with breast cancer and more than 43,000 are projected to die in 2022. Although about 100 times less common than in women, breast cancer also affects men. It is estimated that the lifetime risk of men getting breast cancer is about 1 in 1,000, and the American Cancer Society estimates that approximately 2,710 new cases of invasive male breast cancer will be diagnosed and approximately 530 men will die from breast cancer in 2022.

According to the May 2019 “Global Oncology Trends 2021” report by the IQVIA Institute, the global market for cancer drugs (including immunotherapy drugs) is expected to reach nearly \$269 billion by the end of 2025, growing at a compound annual growth rate (“**CAGR**”) of 10% between 2021 and 2025, of which about 20% is expected to be immuno-oncology drugs.

About 12.9% percent of women will be diagnosed with breast cancer at some point during their lifetime. In 2018, there were an estimated 3,676,262 women living with female breast cancer in the United States. Approximately 81% of cases present as invasive breast cancer. Approximately 6% of new breast cancer diagnoses are Stage IV (metastatic breast cancer (“**MBC**”), which has already spread to other organs). Twenty to thirty percent of all women diagnosed with breast cancer will develop MBC. Breast cancer can be subdivided based on receptor status - the hormone receptors for estrogen (ER) and progesterone (PR), collectively referred to as hormone receptors (HR), and the Her2/neu growth factor receptor (HER2). Based on the latest SEER statistics, 74.6% were found to be HR+/HER2-, 10.8% were triple-negative (HR-/HER2-), 10.5% were HR+/HER2+, and 4.0% were HR-/HER2+.¹

It is estimated that over 150,000 women in the US are living with MBC. For those with metastatic disease at diagnosis, their 5-year survival rate is 27%. For patients who develop MBC after initially having localized disease, if they had a good response to treatment (i.e. a disease-free interval of more than 24 months), their survival rate is similar to that of patients with MBC at initial diagnosis, but if their disease-free interval is less than 24 months, their prognosis is worse.⁴ We currently propose that Bria-IMT’s™ indication will be for the treatment of patients with MBC who have failed at least two lines of therapy. Similarly, another study showed that the median overall survival among patients with de novo stage IV MBC was 39.2 months, while for patients with relapsed disease it was 27.2 months. Median progression free survival after first-line therapy is only 9 months and the survival benefit decreases with subsequent lines of therapy. One study showed that of 386 patients with MBC, 374 (97%) received first-line therapy, 254 (66%) received second-line therapy, 175 (45%) received third-line therapy, and 105 (27%) received therapy beyond third-line.

Recent Developments

On August 4, 2022, the Company announced that it has secured an exclusive license from University of Maryland, Baltimore County (UMBC) to develop and commercialize Soluble CD80 (sCD80) as a biologic agent for the treatment of cancer.

The novel technology, originally developed by Suzanne Ostrand-Rosenberg, Ph.D., Emeritus Faculty at UMBC, and member of BriaCell's scientific advisory board, is titled "Soluble CD80 as a Therapeutic to Reverse Immune Suppression in Cancer Patients" and covered under USPN 8,956,619 B2, USPN 9,650,429 B2, and USPN 10,377,810 B2. In animal models, sCD80 was well-tolerated and stopped tumor growth by potentially restoring natural anti-tumor immunity (see Lucas A Horn, et al. and Samuel T Haile et al. in collaboration with Dr. Ostrand-Rosenberg). Additionally, strong anti-tumor activity of sCD80 has been reported in multiple tumor types (see Lucas A Horn, et al.). Importantly, as demonstrated in the same studies, sCD80's unique actions may involve both awakening and boosting the immune system to recognize and destroy tumor cells.

Under the terms of the agreement, BriaCell gains the worldwide rights to develop and commercialize sCD80, while UMBC maintains ownership of the patents. BriaCell will pay royalties to UMBC upon the commercialization of the product plus patent management costs. The licensing agreement was coordinated by UMBC's Office of Technology Development.

On September 7, 2022, the Company announced a poster presentation at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting, held November 10-12, 2022, in Boston, MA.

The Company's data showed clinical benefit including extended survival time and tumor reductions in heavily pre-treated advanced breast cancer patients who matched our lead candidate, Bria-IMT™, at HLA type/s, and these findings guided the development of further optimized off-the-shelf personalized immunotherapies for advanced breast cancer and other cancers.

On September 14, 2022, the Company announced that it has signed an agreement with Caris Life Sciences® (Caris), a leading molecular science and technology company actively developing and delivering innovative solutions to revolutionize healthcare.

The goal is to develop immunotherapies that are personalized for each patient, and Caris' extensive library of clinical data, cutting-edge biomarker technology, and expertise will be invaluable in achieving our objectives," The Company expects Caris' unique platform to help us identify patients who do not respond to existing treatments and are more likely to benefit from the Company's immunotherapy treatments.

Under the terms of the agreement, Caris will help BriaCell with efficient patient identification, accelerating enrollment for its current Phase I/II clinical trial in advanced metastatic breast cancer of certain genetically defined subgroups. The partnership between BriaCell and Caris leverages Caris' Right-In-Time (RIT) Clinical Trial Network, a group of over 495 oncology sites that are able to quickly identify and enroll eligible patients in biomarker-directed clinical trials. This service offers patients and physicians access to the most cutting-edge precision medicine in development. Additionally, through Caris' comprehensive molecular profiling (Whole Exome and Whole Transcriptome Sequencing), Caris will perform tumor profiling for the patients enrolled in the clinical trial.

On October 12, 2022 the Company announced that it added Mayo Clinic, Jacksonville, Florida as a clinical site in the Phase I/II study of BriaCell's lead candidate, Bria-IMT™, with Incyte's PD-1 inhibitor, retifanlimab, in advanced breast cancer.

On November 10, 2022, the Company announced positive initial efficacy data in its 2021-2022 cohort of 12 advanced breast cancer patients. Disease control, tumor shrinkage, and potential survival benefit were observed amongst 12 patients in the Phase I/IIa clinical study of Bria-IMT™ in combination with Incyte's retifanlimab.

- *Bria-IMT™ regimen in combination with Incyte's retifanlimab produced evidence of disease control, tumor shrinkage, and potential survival benefit amongst BriaCell's recent 12 patient cohort in advanced breast cancer.*
- *The regimen remains well tolerated as recently reported in Phase I evaluation.*

- 70% of patients showed either disease control or progression-free survival (PFS) benefits compared with their last therapy.
- Prior to enrollment, the 12 patients in the cohort had already been unsuccessfully heavily pre-treated with at least 2 prior therapy regimens, further underscoring BriaCell's positive patient outcomes.

This information was summarized in BriaCell's poster session at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting, held November 10-12, 2022, in Boston, Massachusetts. The poster session highlights BriaCell's novel off-the-shelf personalized cellular therapy approach to immunotherapy treatment.

Title: An off-the-shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors.

Abstract **Number:** 257

Location: Omni Boston Hotel, 450 Summer Street, Boston, Massachusetts 02210, Poster Hall, Hall C

Date and Time: November 10, 2022, 9:00 am – 9:00 pm

Bria-IMT™ regimen combined with Incyte's retifanlimab

Seventy percent of evaluable patients participating in the Phase I/IIa clinical study showed either disease control or progression-free survival (PFS) benefits compared with their last therapy regimen. Disease control rate (DCR) of 57% (4/7) was observed in evaluable patients, measured as the percentage of patients who have achieved certain clinical end points (i.e. complete response, partial response and stable disease). DCR is used in cancer clinical trials to measure the clinical effectiveness of a treatment. PFS is the time period during which a patient's cancer does not get worse, commonly used as a key survival and efficacy measurement compared to the PFS values of their previous therapy regimen.

Prior to enrollment in the study, the 12 patients in the cohort had already been unsuccessfully heavily pre-treated or were in the terminal stage of breast cancer, further underscoring the uniquely positive outcome BriaCell's treatment has achieved. The 12 patients had each failed at least 2 prior systemic therapy regimens (including chemotherapy, biological and "targeted" therapy).

Disease control rates of the study are impressive in our view, suggesting robust clinical efficacy of the combination treatment. Importantly, we are very encouraged by the early PFS data in our ongoing study, since it is commonly known in cancer therapy that PFS values typically drop from one therapy to the next in advanced cancers. Please note that the PFS data is early data, as patients continue to remain in the study. The positive PFS trend BriaCell has observed in this patient cohort highlights the effectiveness of BriaCell's treatment without harmful side effects.

The study, recently awarded U.S. Food and Drug Administration fast track designation, continues with additional clinical data forthcoming.

In summary, these findings show evidence of clinical and survival benefits in heavily pre-treated advanced breast cancer patients, suggesting an additive or synergistic effect of Bria-IMT™ in combination with PD-1 inhibitors, and supporting the strategy of using the Bria-IMT™ combination regimen with retifanlimab for the treatment of advanced breast cancer patients.

Evidence of immune system activation by Bria-OTS+™ and Bria-PROS™

BriaCell's poster presentation highlights the development details and activities of BriaCell's next generation (enhanced version) off-the-shelf personalized immunotherapies.

BriaCell has recently developed its novel next generation off-the-shelf personalized immunotherapies, including Bria-OTS+™, and Bria-PROS™, that are designed to produce several immune activating molecules in addition to their original immune activating mechanisms for increased efficacy. This represents a significant advancement in BriaCell's novel off-the-shelf personalized immunotherapy technology.

Both Bria-OTS+™ for advanced breast cancer, and Bria-PROS™ for advanced prostate cancer, were able to activate naïve T cells, suggesting their potential capabilities to produce very strong immune responses in patients. Results show that the very strong immune responses observed may be due to: 1) direct activation of the components of the immune system such as naïve T cells, and 2) indirect activation of the immune system components via production of immune activating molecules.

We are impressed with the data showing very strong immune responses for both Bria-OTS+™ and Bria-PROS™. We expect both Bria-OTS+™ and Bria-PROS™ to boost the immune system response and produce strong anti-tumor responses in patients with advanced breast cancer and prostate cancer, respectively.

Results of Operations for the Three Months Ended October 31, 2022, and 2021

	Three months ended October 31,	
	2022	2021
	(Unaudited)	(Unaudited)
Operating Expenses:		
Research and development expenses	\$ 3,255,215	\$ 875,636
General and administrative expenses	2,147,936	1,409,173
Total operating expenses	5,403,151	2,284,809
Operating loss	(5,403,151)	(2,284,809)
Financial income (expenses), net		
Interest income	188,353	6,305
Interest expense	-	(979)
Change in fair value of warrant liability	4,117,790	(25,254,036)
Foreign exchange gain	(9,533)	34
Total financial income (expenses), net	4,296,610	(25,248,676)
Loss and Comprehensive loss for the period	\$ (1,106,541)	\$ (27,533,485)
Net loss per share – basic and diluted	\$ (0.07)	\$ (1.81)
Weighted average number of shares used in computing net basic and diluted earnings per share of common stock	15,518,018	15,238,646

Research and Development Costs

Research costs are comprised primarily of (i) Salaries and wages to Company employees at our laboratory; and (ii) Clinical trials and investigational drug costs, which include the testing and manufacture of our investigational drugs and costs of our clinical trials.

For the period ended October 31, 2022, research costs amounted to \$3,255,215 as compared to \$875,636 for the period ended October 31, 2021. The rise in cost is attributed to the continued expansion of the Company's clinical trials, the increased activity in the lab, including the hiring of additional lab employees, and the addition of share based compensation (non-cash) expenses.

General and Administrative Expenses

For the period ended October 31, 2022, general and administrative expenses amounted to \$2,147,936 as compared to \$1,409,173 for the period ended October 31, 2021. These increases relate primarily to increased insurance premiums, share based compensation (non-cash), professional fees, and salaries due the hiring more personnel.

Financial income (expenses), net

For the period ended October 31, 2022, financial income, net, amounted to \$4,296,610 as compared to an expense of \$25,248,676 for the period ended October 31, 2021. The large difference is due to the change in value of the Company's warrant liability which amounted to a gain of \$4,117,790 in the three-month period ending October 31, 2022 and a loss of \$25,254,036 in the three-month period ending October 31, 2021. The Company recorded \$188,353 in interest income in the three-month period ending October 31, 2022 as compared to \$6,305 in the three-month period ending October 31, 2021.

Loss for the period

The Company reported a loss for the period ended October 31, 2022, of \$1,106,541, as compared to \$27,533,485 for the period ended October 31, 2021. The loss in 2022 is due to a significant decrease in the fair value of the warrant liability offset by increased operational spending. The higher loss in the prior period is due to the large increase in fair value of the warrant liability.

Going Concern Uncertainty

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.

As of October 31, 2022, the Company has total assets of \$38,450,320 (July 31, 2022 - \$42,577,041) and a positive working capital balance of \$37,249,747 (July 31, 2022 - \$41,405,613).

The Company is planning to finance its research and developmental activities from its existing and future working capital resources and will continue to evaluate additional sources of capital and financing. The Company believes that its existing capital resources will be adequate to satisfy its expected liquidity requirements for at least twelve months from the issuance of the consolidated financial statements.

Liquidity and Capital Resources

As of October 31, 2022, the Company has working capital of \$37,249,747 (July 31, 2022 - \$41,405,613) and an accumulated deficit of \$61,456,378 (July 31, 2022 - \$60,349,837).

As of October 31, 2022, the Company's capital resources consist primarily of cash and cash equivalents, comprising mostly of cash on deposit with banks, investments in money market funds, investments in U.S. government securities, U.S. government agency securities, and investment grade corporate debt securities. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements.

Historically, the Company has financed its operation through private and public placement of equity securities, as well as debt financing. The Company's ability to fund its longer-term cash requirements is subject to multiple risks, many of which are beyond its control. The Company intends to raise additional capital, either through debt or equity financings in order to achieve its business plan objectives. Management believes that it can be successful in obtaining additional capital; however, there can be no assurance that the Company will be able to do so. There is no assurance that any funds raised will be sufficient to enable the Company to attain profitable operations or continue as a going concern. To the extent that the Company is unsuccessful, the Company may need to curtail or cease its operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful.

During the period ended October 31, 2022, the Company's overall position of cash and cash equivalents decreased by \$18,038,110 from the period ended October 31, 2021 (including effects of foreign exchange). This decrease in cash can be attributed to the following:

The Company's net cash used in operating activities during the period ended October 31, 2022, was \$3,542,382 as compared to \$1,778,599 for the period ended October 31, 2021.

Cash used in financing activities for the period ended October 31, 2022, was \$47,294 as compared to \$nil for the period ended October 31, 2021.

Off-Balance Sheet Arrangements

None.

Tabular Disclosure of Contractual Obligations

None.

Critical Accounting Policies and Estimates

There have been no material changes to our critical accounting policies and estimates from the information provided in the MD&A section in our Annual Report.

New Accounting Policies Adopted

The Company did not adopt any new accounting policies during the period ended October 31, 2022.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company's financial instruments consist of cash and cash equivalents, amounts receivable, investments, trade payable, and accrued expenses and other payables. 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 a portion of the Company's transactions occur in Canadian Dollars (mainly costs relating to being a public company in Canada), and the Company's functional and presentation currency is the US 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:

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.

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 of October 31, 2022, the Company has total assets of \$38,450,320 (July 31, 2022 - \$42,577,041) and a positive working capital balance of \$37,249,747 (July 31, 2022 - \$41,405,613).

Market Risk

Interest rate risk

Interest Rate risk is the risk that the fair value of a financial instrument will fluctuate because of changes in market interest rates. The Company does not believe it is exposed to material interest rate risk as it has no interest-bearing debt.

Price risk

As the Company has no revenues, price risk is remote.

Exchange risk

The Company is exposed to foreign exchange risk as a portion of the Company's transactions occur in Canadian Dollars (mainly costs relating to being a public company in Canada) and, therefore, the Company is exposed to foreign currency risk at the end of the reporting period through its Canadian denominated accounts payable and cash. As of October 31, 2022, a 5% depreciation or appreciation of the Canadian dollar against the US dollar would not have a material effect on the in total loss and comprehensive loss.

Fair Values

The carrying values of cash and cash equivalents, amounts receivable, trade payable, and accrued expenses and other payables approximate their fair values due to their short terms to maturity.

The cash and cash equivalents are valued using quoted market prices in active markets.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal accounting and financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer and principal accounting and financial officer have concluded that as of October 31, 2022, our disclosure controls and procedures were not effective as a result of material weaknesses in our internal control over financial reporting. We are implementing plans to improve these material weaknesses, including implementation of independent review and approval of transactions and reconciliations in certain processes through hiring additional personnel and segregating duties amongst our team. We are instituting processes to document and retain evidence to support reviews and reconciliations.

Changes in Internal Control over Financial Reporting

There have not been material changes in our internal control over financial reporting during the quarter ended October 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except for our remediation efforts described above.