

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, 2024 (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 2024 in comparison to the first quarter of fiscal 2023.
- *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 is a clinical-stage biotechnology company that is developing novel immunotherapies to transform cancer care. Immunotherapies have come to the forefront in the fight against cancer as they harness the body’s own immune system to recognize and destroy cancer cells. The Company is currently advancing its Bria-IMT™ targeted immunotherapy in combination with an immune check point inhibitor (Retifanlimab) in a pivotal Phase 3 study in metastatic breast cancer. Bria-IMT™ is currently under Fast Track Designation by the U.S. Food and Drug Administration (the “FDA”) intended to accelerate the review process of novel treatments that address unmet medical needs. Positive completion of the pivotal study, following review by FDA, could lead to full approval of the Bria-IMT™ immune checkpoint inhibitor combination in metastatic breast cancer. BriaCell reported benchmark-beating patient survival and clinical benefit in metastatic breast cancer with median overall survival of 13.4 months in BriaCell’s metastatic breast cancer patients vs. 6.7-9.8 months for similar patients reported in the literature in its Phase 2 study of Bria-IMT™ combination study with retifanlimab at the 2023 San Antonio Breast Cancer Symposium. A completed Bria-IMT™ Phase 1 combination study with retifanlimab (an anti-PD1 antibody manufactured by Incyte) confirmed tolerability and early-stage efficacy. BriaCell is also developing personalized off-the-shelf immunotherapies, Bria-OTS™ and Bria-OTS+™, which provides a platform technology to develop personalized off-the-shelf immunotherapies for numerous types of cancer, and a soluble CD80 protein therapeutic which acts both as a stimulator of the immune system as well as an immune checkpoint inhibitor.

Recent Developments

On October 15, 2024, the Company provided an update on its pivotal Phase 3 study in metastatic breast cancer - 35 clinical sites (18 main and 17 satellite) are active and enrolling patients. Additional sites are in various stages of start-up. Interim data will be analyzed once 144 events (deaths) occur, comparing the overall survival (OS) in patients treated with the Bria-IMT™ combination regimen versus those treated with physician's choice as the primary endpoint. Positive results of the pivotal Phase 3 study could result in full approval and marketing authorization for Bria-IMT™ in MBC patients. Secondary analyses include comparison of the Bria-IMT™ combination regimen vs Bria-IMT™ monotherapy. BriaCell recently announced impressive Phase 2 survival data in a similar MBC patient population. The Bria-IMT™ combination regimen has received FDA Fast Track designation.

On October 22, 2024, the Company reported that in the Company's Phase 2 clinical study, patients treated with the same Bria-IMT™ regimen formulation being used in the ongoing Phase 3 pivotal trial experienced a one-year survival rate of 55% (i.e. 55% of patients remain alive at least one year after starting on the study). This rate exceeds the survival data of the current standard of care for similar patients (see Table 1). Notably, 4 of 13 patients recruited in 2022 remain in survival follow-up as well.

On November, 21, 2024, the Company announced that the first patient was dosed in its Phase 1/2 study (ClinicalTrials.gov identifier: NCT06471673) to evaluate the safety and efficacy of Bria-OTS™, BriaCell's personalized next generation immunotherapy. The study will investigate Bria-OTS™ alone and in combination with immune check point inhibitor tislelizumab® (manufactured and supplied by BeiGene, Ltd.) for the treatment of metastatic breast cancer. Bria-OTS™ is an enhanced form of Bria-IMT™, currently in pivotal Phase 3 study for metastatic breast cancer.

On November 23, 2024, Marc Lustig resigned from the board of directors of the Company.

On December 13, 2024, the Company closed a public offering for the purchase and sale of 7,400,000 common shares of the Company and warrants to purchase up to an aggregate of 7,400,000 common shares of the Company for aggregate gross proceeds of approximately \$5.55 million before deducting underwriting discounts, commissions, and other offering expenses (the "December 2024 Offering"). Each common share was sold together with one warrant to purchase one common share at a combined purchase price of \$0.75. The warrants have an exercise price of \$0.9375 per share, and are immediately exercisable for a period of five years from the closing date. In addition, the Company issued 370,000 agent warrants. The agent warrants are immediately exercisable for a period of five years from the closing date at an exercise price of \$0.9375.

Results of Operations for the Three Months Ended October 31, 2024, and 2023

	Three months ended October 31,	
	2024	2023
Operating expenses:		
Research and development expenses	\$ 3,665,341	6,857,257
General and administrative expenses	1,487,491	1,645,771
Total operating expenses	5,152,832	8,503,028
Operating loss	(5,152,832)	(8,503,028)
Financial income, net	11,714	179,822
Change in fair value of the warrant liability	(616,643)	14,282,078
Share of loss on equity investment	(71,515)	-
Net income (loss) for the period	\$ (5,829,276)	\$ 5,958,872
Net loss attributable to non-controlling interest	(27,101)	(42,671)
Net income (loss) for the period attributable to BriaCell	(5,802,175)	6,001,543
Net income (loss) per share attributable to BriaCell – basic	\$ (0.22)	\$ 0.38
Net income (loss) per share attributable to BriaCell – diluted	(0.22)	(0.50)
Weighted average number of shares used in computing net basic earnings per share of common stock	26,641,036	15,619,676
Weighted average number of shares used in computing net diluted earnings per share of common stock	26,641,036	16,674,891

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.

The following is a breakdown of our research and development costs by nature of expenses:

	Three months ended October 31,	
	2024	2023
Clinical trial sites and investigational drug costs	\$ 2,439,667	\$ 5,397,438
Wages and salaries	949,089	1,020,725
Laboratory Rent	114,330	88,480
Supplies	99,430	89,023
Depreciation	22,839	-
Professional fees	7,268	3,782
Share-based compensation	32,718	257,809
	<u>\$ 3,665,341</u>	<u>\$ 6,857,257</u>

For the three-month period ending October 31, 2024, research costs amounted to \$3,665,341, a significant decrease from the \$6,857,257 incurred during the same period in 2023. This reduction was primarily driven by lower clinical trial sites and investigational drug costs, which decreased from \$5,397,438 in 2023 to \$2,439,667 in 2024. The decrease reflects the conclusion of the Bria-IMT™ Phase 1/2a trial and a focus on optimizing expenditures for the pivotal Phase 3 trial. Wages and salaries decreased slightly, from \$1,020,725 in 2023 to \$949,089 in 2024, reflecting resource allocation adjustments. Laboratory rent increased to \$114,330 in 2024, up from \$88,480 in 2023, due to expanded use of facilities to support ongoing research. Supplies also increased, from \$89,023 in 2023 to \$99,430 in 2024, driven by higher operational needs. Depreciation expenses of \$22,839 were recognized in 2024, reflecting investments in capital assets to support research activities. Professional fees increased to \$7,268 in 2024, compared to \$3,782 in 2023, primarily due to consulting and support for clinical operations. Notably, share-based compensation expenses decreased significantly, from \$257,809 in 2023 to \$32,718 in 2024, contributing to the overall reduction in research and development expenses.

Our clinical trial expenses are broken down as follows:

	Three months ended October 31,	
	2024	2023
Bria-IMT™ Pivotal Phase 3 study	\$ 2,185,543	\$ 2,278,258
Bria-IMT™ Phase 1/2a	142,496	1,214,440
Indirect research and development expenses allocated to trials	111,628	134,592
	<u>\$ 2,439,667</u>	<u>\$ 3,627,290</u>

Clinical trial expenses for the three months ended October 31, 2024, were \$2,439,667, compared to \$3,627,290 during the same period in 2023. The decrease in expenses is primarily attributable to the conclusion of patient recruitment and related activities in the Bria-IMT™ Phase 1/2a clinical trial in fiscal 2024. This reduction in costs aligns with our transition to the pivotal Phase 3 study of Bria-IMT™, which has become the primary focus of our clinical development efforts.

For the three-month period ending October 31, 2024, Bria-IMT™ Pivotal Phase 3 Study costs amounted to \$2,185,543, remaining consistent with the prior year's \$2,278,258. This consistency reflects our strategic decision to optimize spending while focusing expenditures on this pivotal trial, underscoring our commitment to prioritizing the Phase 3 study as the cornerstone of our clinical development program. Resources were effectively allocated toward patient recruitment, trial operations, and preparation for key milestones.

For the three-month period ending October 31, 2024, Bria-IMT™ Phase 1/2a costs amounted to \$142,496, a significant decrease compared to \$1,214,440 during the same period in 2023. This decrease is attributed to the trial's conclusion in fiscal 2024, with only minimal remaining expenses related to final data analysis and study close-out activities.

For the three-month period ending October 31, 2024, indirect research and development expenses allocated to trials amounted to \$111,628, compared to \$134,592 in the prior year. This reduction is primarily due to streamlined trial operations and a shift in resource allocation toward the pivotal Phase 3 study.

We remain focused on advancing the pivotal Phase 3 study of Bria-IMT™ in advanced breast cancer and continue to direct resources accordingly to ensure its timely progression.

General and Administrative Expenses

For the three-month period ending October 31, 2024, general and administrative expenses amounted to \$1,487,491, showing a decrease from \$1,645,771 in the same period of 2023. The decrease in general and administrative expenses primarily stems from lower insurance premiums, professional fees and share-based compensation expenses. The Company has reduced general and administrative expenses in order to devote more resources to its clinical program.

Financial income (expenses), net

For the three-month period ending October 31, 2024, net financial income amounted to \$11,714, a significant decrease from the \$179,822 recorded in the same period of 2023. Financial income for the three-month period ending October 31, 2024 primarily consists of interest income of \$13,050, offset by a foreign exchange loss of \$1,336. In comparison, For the three-month period ending October 31, 2023, interest income was \$190,815, while foreign exchange losses totaled \$10,993. The decrease in financial income from 2023 to 2024 reflects lower interest income due to reduced cash and cash equivalents available for investment in interest-bearing funds.

Profit (loss) for the period

For the three-month period ended October 31, 2024, the Company reported a loss of \$5,829,276 compared to a gain of \$5,958,872 for the same period in 2023. The loss in the three-month period ended October 31, 2024, primarily resulted from the significant change in the fair value of the warrant liability, which accounted for a loss of \$616,643 in 2024 compared to a gain of \$14,282,078 in 2023. This highlights the substantial impact that warrant liability valuation has on the Company's overall financial performance, despite decreased operational spending during the period, particularly in research and development.

Liquidity, Capital Resources and 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, 2024, and a positive working capital balance of \$3,230,459 (July 31, 2024 negative balance of \$3,807,303).

As of October 31, 2024, the Company has total assets of \$10,414,330 (July 31, 2024 - \$5,872,261), a positive working capital of \$3,230,459 (July 31, 2024 – negative balance of \$3,807,303) and an accumulated deficit of \$91,245,872 (July 31, 2024 - \$85,443,697).

As of October 31, 2024, 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. To this end, for several months during calendar year 2024, certain directors and officers agreed to defer payment of their directors' fees/compensation until we completed a financing, after which, these fees were paid in full. Further, certain officers have indicated their willingness to receive a portion of their compensation in equity of the Company, subject to applicable Nasdaq rules. In addition, we continue to reduce expenditure on certain non-core activities whilst maintaining our focus on our Phase 3 Bria-IMT™ pivotal study in advanced metastatic breast cancer.

During the period ended October 31, 2024, the Company's overall position of cash and cash equivalents increased by \$4,930,176 from the period ended July 31, 2024 (including effects of foreign exchange). This increase in cash can be attributed to the following:

The Company's net cash used in operating activities during the period ended October 31, 2024, was \$6,955,076 as compared to \$7,605,245 for the period ended October 31, 2023.

Cash gained in financing activities for the period ended October 31, 2024, was 11,960,252 as compared to nil for the period ended October 31, 2023.

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, 2024.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

The Company's financial instruments consist of cash and cash equivalents, investments, warrant liability, short term loans, 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, 2024, the Company has total assets of \$10,414,330 (July 31, 2024 - \$5,872,261) and a positive working capital balance of \$3,230,459 (July 31, 2024 - negative working capital balance of \$3,807,303).

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. Loans payable include both fixed and variable interest rates; however, the Company does not believe it is exposed to material interest rate risk.

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, 2024, 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, trade payable, warrant liability, short term loans, and accrued expenses and other payables approximate their fair values due to their short terms to maturity.

Cash and cash equivalents are valued using quoted market prices in active markets. The fair value of the warrant liability is determined based on the nature of the warrant. For publicly traded warrants we use the quoted market price and for all other warrants we use the Black-Scholes pricing model.

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 Securities Exchange Act of 1934 under the Securities Exchange Act of 1934, as amended, or 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, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

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, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

None.