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BriaCell Therapeutics Corp. (BCTX: NASDAQ)

BCTX: Pivotal Study Protocol Cleared

We employ a DCF model and a 15% discount rate to generate our valuation. With regard to regulatory approval and commercialization, our model applies a success probability of 20% for BRIA-IMT and 8% for Bria-OTS in advanced breast cancer. The model includes contributions from the United States and rest of world.

Current Price (7/7/2023)	$6.44
Valuation	**$15.00**

OUTLOOK

BriaCell Therapeutics is a clinical stage oncology-focused biotechnology company using cell-based immunotherapies to target breast and other cancers. The approach stimulates a cancer fighting immune response to destroy tumor cells. Lead candidate Bria-IMT™ is advancing in combination with other therapies including checkpoint inhibitors to combat breast cancer. Secondary candidate Bria-OTS™ addresses variation between patients with breast cancer and is based on a patient's human leukocyte antigen (HLA) type. If successful, this product could address almost all third-line patients.

In addition to Bria-IMT and Bria-OTS, the company offers a portfolio of other preclinical assets addressing prostate, non-small cell lung, melanoma and other cancers. In clinical work to date, BriaCell has shown a strong correlation between the efficacy of Bria-IMT and patients that have a close HLA match with the therapeutic cells.

BriaCell is conducting a Phase I/IIa combination study and has released interim data demonstrating effective immune response and disease control in heavily pre-treated patients. We anticipate start of a pivotal trial in mid-2023 and BLA submission to regulatory authorities in 2025.

SUMMARY DATA

52-Week High	**8.37**
52-Week Low	**4.23**
One-Year Return (%)	**6.8**
Beta	**1.69**
Average Daily Volume (sh)	**126,598**
Shares Outstanding (mil)	**16.0**
Market Capitalization ($mil)	**103**
Short Interest Ratio (days)	**9.8**
Institutional Ownership (%)	**15.2**
Insider Ownership (%)	**23.7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**N/A**
P/E using 2024 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2024					$0.0 E
2025					$0.0 E

Earnings per Share

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2022	-$0.16 A	-$0.24 A	-$0.32 A	-$1.05 A	-$1.73 A
2023	-$0.07 A	-$0.77 A	-$0.32 A	-$0.36 E	-$1.52 E
2024					-$1.50 E
2025					-$1.10 E

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WHAT'S NEW

Third Quarter Fiscal Year 2023 Operational and Financial Results

On June 14th 2023, BriaCell Therapeutics Corp. (NASDAQ: BCTX) reported third quarter fiscal year 2023 financial and operational results. The results for the quarter ending April 30, 2023 were reported in its Form 10-Q filing with the SEC. Since our previous update, BriaCell has announced a strategic investment with Prevail Partners and a clinical alliance with Prevail InfoWorks, which are separate but related entities. The former provided a $4 million investment, signaling optimism over the potential for the upcoming Bria-IMT trial and the latter will serve as the CRO for the upcoming pivotal trial in advanced metastatic breast cancer, whose design was recently cleared by the FDA. Other news includes the anticipated spinout of BriaPro Therapeutics which will shift several preclinical assets into a separate entity.

Highlights for fiscal year 2023 to-date include:

- License secured to commercialize CD80 from UMBC – August 2022
- Trial enrollment assistance with Caris – September 2022
- Presentation of multiple posters at San Antonio Breast Cancer Symposium – December 2022
- Bria-OTS patent issued for Whole-cell Cancer Vaccines and Methods for Selection – January 2023
- End of Phase II meeting with FDA for Bria-IMT – January 2023
- Bria-OTS trial launch – 2Q:23
- Presentation of multiple posters at AACR – April 2023
- Strategic Investment and Clinical Alliance with Prevail – May 2023
- Announced arrangement to spin out Bria Pro Therapeutics – May 2023
- FDA clearance of Bria-IMT study design for pivotal trial in advanced metastatic breast cancer – June 2023

BriaCell produced no revenues in its fiscal third quarter and incurred operating expense of ($5.7) million, yielding a net loss of ($4.9) million, or ($0.32) per share. For the second quarter ending April 30, 2023 versus the same ending April 30, 2022:[1]

- Research & development expense was $3.9 million, up 52% from $2.5 million, attributed to increased clinical activity for the 46-subject Bria-IMT trial, increased wages and salaries, greater laboratory activity, including the hiring of additional employees, and higher supply usage. Spending on preclinical projects and Chemistry, Manufacturing and Control (CMC) was also significantly higher;
- General & administrative expenses totaled $1.8 million, down 21% from $2.3 million, due to a reduction in share-based compensation;
- Financial income totaled $782,000 with a positive change in warrant liability related to a decrease in the stock price over the measurement period;
- Net loss totaled ($4.9) million vs. ($4.8) million, which was a loss per share of ($0.32) in both periods.

As of April 30, 2023, cash and equivalents totaled $28.2 million compared to $41.0 million at the end of the fiscal year last July. Cash burn year to date totaled ($12.8) million. Financing cash flows were minimal and related to a small share and warrant buyback minimally offset by proceeds from warrant exercise.

BriaCell Gains Clearance for Bria-IMT Study Protocol

On June 27th 2023, BriaCell Therapeutics Corp. (NASDAQ: BCTX) announced that the protocol for its pivotal registrational trial for Bria-IMT in advanced metastatic breast cancer had been cleared by the FDA. Bria-IMT will be administered in combination with a checkpoint inhibitor in the active arm and compared against the control arm which will include treatment of the physician's choice. The checkpoint inhibitor that will be used has not yet been determined. However, we expect to see that one of the previous checkpoints that have been evaluated with Bria-IMT will

[1] We provide comparative year over year analysis using information as originally reported. 2Q:22 was reported in a 6-K as a foreign issuer and fell under different accounting standards.

be used, as there is safety data related to each in combination with BriaCell's drug. Both Incyte's retifanlimab (Zynyz)[2] and Merck's Keytruda have been tested with Bria-IMT in clinical trials.

Final details for the pivotal trial have not yet been announced and include the number of subjects that will be enrolled and the checkpoint inhibitor that will be used. BriaCell is undertaking a statistical analysis that will identify the optimal study enrollment number. There are expected to be 100 sites in the US, Canada and potentially in Western Europe to accommodate the anticipated enrollees. Fast track status was granted by the FDA in April 2022. The status should increase the frequency of meetings between BriaCell and the FDA and open the door for other benefits including Accelerated Approval, Priority Review and Rolling Review if appropriate.

Based on management commentary, we expect the trial to begin enrollment this summer. Both enrollment and patient evaluation are expected to take approximately twelve months apiece suggesting that topline from the trial could be available by autumn 2025.

Exhibit I – BriaCell Pipeline[3]

Therapeutic	Indication	Preclinical	Phase 1	Phase 2	Phase 3	2023 Milestones
Bria-IMT™ CPI Combination	Advanced Metastatic Breast Cancer	Phase 2 (Fast Track)				Ongoing Phase 1/2a Safety & Efficacy Data Registration Study Initiation
Bria-OTS™	Breast Cancer					Phase 1/2 Initiation
Bria-Pros™	Prostate Cancer					IND in Preparation
Bria-Lung™	Non-Small Cell Lung Cancer					IND in Preparation
Bria-Mel™	Melanoma					IND in Preparation
sCD80	Solid Tumors					IND in Preparation

Prevail Partners Strategic Investment

BriaCell announced a strategic investment and clinical alliance with Prevail Partners and Prevail InfoWorks in May and followed up shortly after with a press release confirming receipt of a $4 million strategic investment from Prevail Partners. The relationship involves both a strategic investment fund (Prevail Parners) and a contract research organization (CRO) (Prevail InfoWorks).

Prevail Partners will purchase 463,408 BriaCell common shares at a price of $8.63, generating $4.0 million in process. The price is a 20% premium to the trailing 30-day volume-weighted average price (VWAP) prior to the transaction. Prevail InfoWorks will manage the upcoming pivotal trial for Bria-IMT in metastatic breast cancer. The Philadelphia, Pennsylvania-based CRO uses its Single Interface integrated real-time data analytics platform to provide clinical support and provide real-time data analysis.

Spinout of BriaPro Therapeutics Corp.

In a May 25th press release, BriaCell announced that it will spin out a new entity to be called BriaPro Therapeutics Corp. The new company will hold the intellectual property and development obligations for BriaCell's preclinical assets: Bria-TILsRx™ and protein kinase C delta (PKCδ) inhibitors for multiple indications including cancer.

Bria-TILsRx
Bria-TILsRx are being developed as potential immunotherapies for cancer. Bria-Pro features two TILsRx novel candidates which are multi-specific binding reagents designed to act as potent immune cell activators and/or immune checkpoint inhibitors. The assets are expected to selectively target and destroy cancer cells without harming normal (non-cancerous) cells. This mechanism may be associated with less severe side effects for the treated cancer patients compared with those of alternative therapies.

[2] Zynyz (retifanlimab-dlwr) is a humanized monoclonal antibody targeting programmed death receptor-1 (PD-1), for the treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma. The Biologics License Application (BLA) for Zynyz was approved under accelerated approval by the U.S. FDA in March 2023.
[3] Source: BriaCell Spring 2023 Corporate Presentation

PKCδ
Protein kinase C delta (PKCδ), also called novel PKC, is associated with a number of diseases including cancer, cardiovascular diseases, neurodegenerative disorders and inflammation. PKCδ inhibitors have been shown to be effective treatments for several animal models of cancer and other diseases. The cytoplasmic enzyme plays a crucial role in cellular signaling pathways, particularly in regulating cell growth, differentiation, proliferation, and apoptosis. BriaPro's highly selective PKCδ inhibitors may be developed as candidates for multiple disease indications including several tumor types.

In a March 30 press release, BriaCell first indicated its intention to spin out BriaPro's preclinical assets. The new entity is expected to be majority-owned, controlled, and governed by BriaCell and owned by its shareholders of record who will receive equity shares. Management has identified "significant independent value" from these assets and will allow their development to proceed under a separate balance sheet and with its own focus.

Each BriaCell share will receive one BriaPro share, and BriaCell shareholders will initially comprise one-third of BriaPro ownership. BriaCell warrant and option holders will receive one BriaCell share and one BriaPro share upon exercise. The new company will become an unlisted reporting issuer in Canada after shareholder approval is granted in a vote that is expected to take place later in July.

BriaCell Poster Presentations at the American Association for Cancer Research (AACR) Annual Meeting

BriaCell Therapeutics presented multiple posters at the American Association for Cancer Research (AACR) Annual Meeting held in Orlando, Florida, April 14 – 19, 2023. The posters provided updated information and additional details on the Bria-IMT clinical trial and development of Bria-OTS. We summarize the posters below and provide a link to the material.

Poster 1
The title of the first poster is Whole Cell Antigen Presenting Immune Stimulating Cells (Bria-IMT) for the Treatment of Metastatic Breast Cancer. It noted that 15 of the 18 patients recruited since the study reopened in 2021 were alive. It also examined whether the strength of a patient's immune system as measured through candida response was linked to delayed-type hypersensitivity (DTH). It found that progression free survival (PFS) was not materially different between subjects who responded and did not respond to the candida test. However, it did find that there was a substantial difference in PFS between patients that presented a DTH reaction. The takeaway is that sicker patients will also respond to Bria-IMT despite a weaker immune system as indicated by the candida response.

Poster 2
The poster two title is Engineering semi-allogeneic whole cell cancer vaccines with enhanced immunogenicity for the treatment of advanced solid tumors. The document examined the potency of Bria-OTS and its effort to induce T cell responses in a variety of tumors. Bria-OTS (off the shelf) was able to stimulate naïve T cells in an antigen-specific, HLA restricted manner, which is expected to increase potency when in the clinic. Tumor cell lines that express co-stimulatory molecules and immuno-modulatory cytokines are able to activate naïve T cells. Other study observations conclude that tumor cell lines expressing transgenic HLAs are able to induce T Cell Receptor (TCR) signaling.

Poster 3
The title of the third poster is Tumor Macrophage Fusion Cells detected in the circulation of metastatic breast cancer patients is prognostic for rapid progression and death. Creatv MicroTech developed this analysis which has been examining circulating tumor cells (CTCs) and cancer associated macrophage-like (CAML) cells on behalf of BriaCell for some time. When tumor cells and macrophages fuse, they create tumor macrophage fusion (TMF) cells which can serve as prognosticators for outcomes in the context of cancer therapy. The CAMLs clean up the cancer cells; however, the tumor may negate this process by fusion of the CAMLs with the cancer cells. The poster identifies six types of fusion that are markers for a worse progression free survival (PFS) and overall survival (OS). The tumor antigens are expressed on the cancer cells in a way that makes the tumor microenvironment more permissive for cancer proliferation. The findings do not have any direct implications for BriaCell's work; however, they could provide support for a biomarker to identify more responsive patients.

Poster 4
Poster four is entitled Micronuclei in Circulating Stromal Cells Correlated with PD-L1 Expression and Predicts Progression in Metastatic Breast Cancer. It examines the predictive ability of micronuclei in circulating stromal cells for metastatic breast cancer patients on clinical outcomes. Micronuclei are small nuclei that can be formed during cell division and may indicate the presence of DNA damage. Findings in the poster noted that micronuclei were identified in 59% of circulating stromal cells and that these cells had a significantly higher PD-L1 expression than the cir-

culating stromal cells that did not have micronuclei. There was also a relationship between the number of micronuclei and PD-L1 expression and higher presence of micronuclei was associated with worse PFS and OS. The summary concluded that micronuclei may indicate survivability of cancer cells and greater amounts of micronuclei are associated with worse progression rates.

Bria-IMT Interim Update

A February 23rd update for the Phase II trial evaluating Bria-IMT in advanced metastatic breast cancer patients was provided demonstrating the strong survival benefits observed in trial participants. Nine of eleven (82%) women in the initial cohort who were dosed Bria-IMT were reported as still alive.

BriaCell enrolled eleven subjects in 2021 and 2022 and reported that 82% of the patients (9/11) remain alive from the initial dosing. 64% (7/11) presented either disease control or progression free survival (PFS) benefits compared with their prior lines of therapy. This suggests a clinical benefit to these patients who have exhausted other lines of approved therapy and may only survive weeks to months without treatment.[4] The interim readout also identified a median PFS for the cohort of 3.5 months and pointed out that Bria-IMT is well tolerated with no dose limiting toxicities.

As of the date of the press release in late February, an additional nine patients have been screened or enrolled in the study, adding to the twelve announced in December 2022. Concurrently, BriaCell is taking advantage of its Fast Track status to discuss pivotal trial design with the FDA. The strong survival data generated provides confidence that the primary endpoint of survival will be met in the upcoming pivotal trial.

Other Miscellaneous Events

Shareholder Meeting
In a February 9th press release, BriaCell announced the results of its shareholder meeting. MNP LLP were appointed as auditors for the company over the next year and directors were elected. A new omnibus equity incentive plan was approved and quorum rules were approved that require a minimum of 1/3 of all shares to be represented by person or proxy to constitute a proxy or remove the quorum exception for succeeding meetings.

Exhibit II – BriaCell Development Timeline[5]



Summary

BriaCell continues to progress towards its pivotal trial for Bria-IMT in metastatic breast cancer and is expected to begin the study shortly. A CRO has been identified and a related investment company has placed $4 million with BriaCell to support its clinical endeavors. Trial design is near finalization and the FDA has cleared the study protocol. We expect to see first enrollees in the next few months and a 24-month trial duration. BriaCell has also created a new company which will hold several earlier stage immuno-oncology assets. The separate entity will be called BriaPro Therapeutics and is waiting on several administrative steps and a shareholder vote before being spun out as an unlisted reporting issuer in Canada. We maintain our valuation of $15.00 per share.

[4] Patients enrolled in the trial had failed an average of five other treatments prior to enrolling in the BriaCell study.
[5] Source: BriaCell Spring 2023 Corporate Presentation

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement[6]

BriaCell Therapeutics Corp	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth								
Research & Development	$8,021	$3,255	$3,053	$3,861	$3,800	$13,969	$18,945	$12,250
General & Administrative	$7,267	$2,148	$1,433	$1,816	$2,020	$7,417	$8,200	$8,550
Share Based Compensation	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($15,289)	($5,403)	($4,486)	($5,677)	($5,820)	($21,387)	($27,145)	($20,800)
Operating Margin								
Other Items	($11,550)	$4,297	($7,395)	$782	$0	($2,317)	$0	$0
Fx Translation	$0	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($26,839)	($1,107)	($11,882)	($4,895)	($5,820)	($23,704)	($27,145)	($20,800)
Provision for Income Tax	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	**($26,839)**	**($1,107)**	**($11,882)**	**($4,895)**	**($5,820)**	**($23,704)**	**($27,145)**	**($20,800)**
Net Margin								
Reported EPS	**($1.73)**	**($0.07)**	**($0.77)**	**($0.32)**	**($0.36)**	**($1.52)**	**($1.50)**	**($1.10)**
YOY Growth								
Basic Shares Outstanding	15,494	15,518	15,518	15,518	16,002	15,639	18,100	18,900

Source: Company Filing // Zacks Investment Research, Inc. Estimates

[6] Financial statement information presents data as originally reported.

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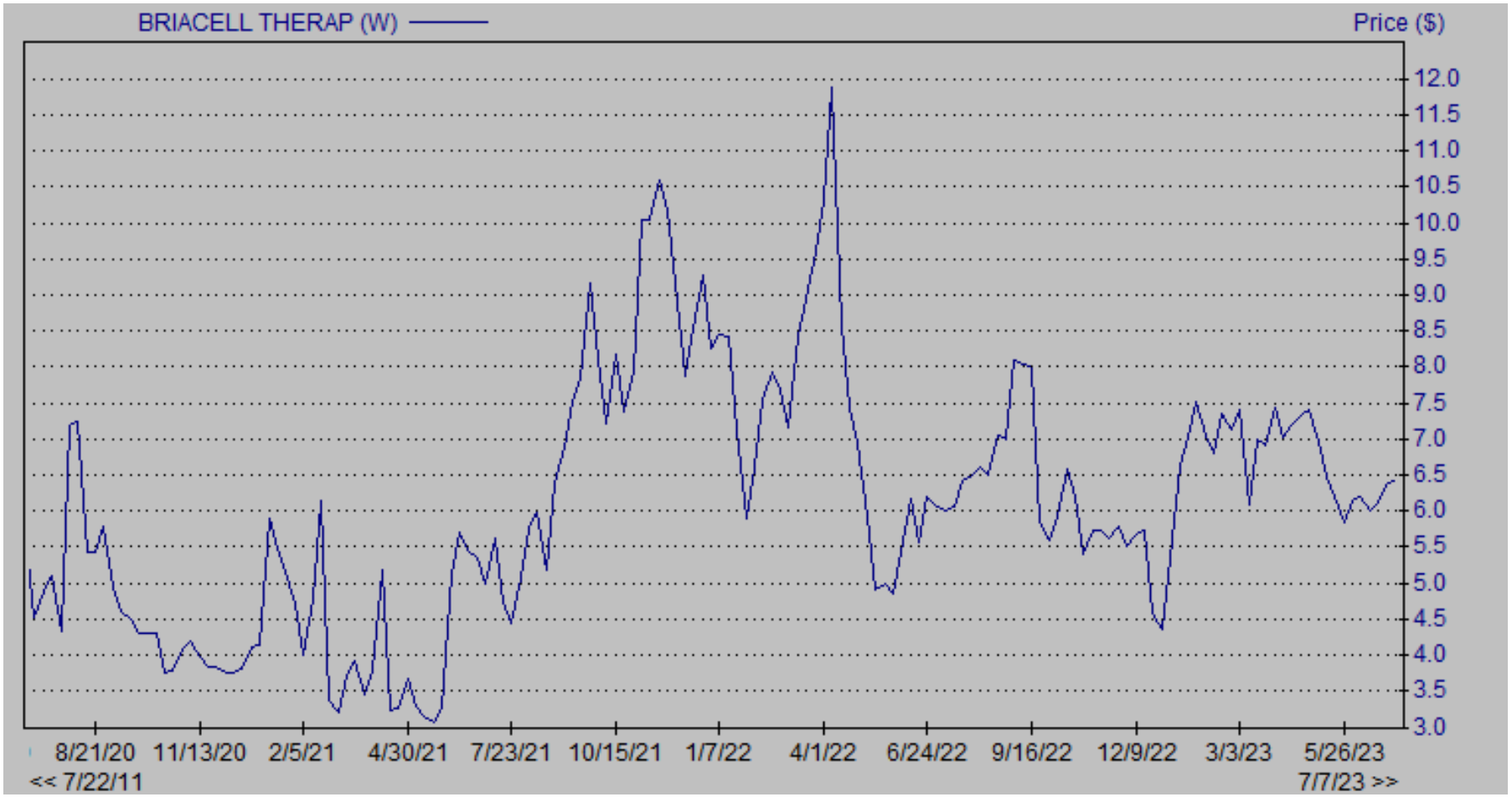
HISTORICAL STOCK PRICE

BriaCell Therapeutics Corp. – Share Price Chart[7]



[7] Source: Zacks Research System

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