

BriaCell Therapeutics Corp.

(BCTX: NASDAQ)

BCTX: Posters Galore at AACR

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 (4/26/2023) **\$6.99**
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 2023 and BLA submission to regulatory authorities in 2025.

SUMMARY DATA

52-Week High **8.37**
 52-Week Low **4.06**
 One-Year Return (%) **8.9**
 Beta **1.68**
 Average Daily Volume (sh) **157,962**

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

Shares Outstanding (mil) **15.5**
 Market Capitalization (\$mil) **108.3**
 Short Interest Ratio (days) **15.4**
 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**

ZACKS ESTIMATES

Revenue

(In millions of USD)

| | Q1 | Q2 | Q3 | Q4 | Year |
|------|---------|---------|---------|---------|---------|
| | (Oct) | (Jan) | (Apr) | (Jul) | (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 E | \$0.0 E | \$0.0 E |
| 2024 | | | | | \$0.0 E |
| 2025 | | | | | \$0.0 E |

Earnings per Share

| | Q1 | Q2 | Q3 | Q4 | Year |
|------|-----------|-----------|-----------|-----------|-----------|
| | (Oct) | (Jan) | (Apr) | (Jul) | (Jul) |
| 2022 | -\$0.16 A | -\$0.24 A | -\$0.32 A | -\$1.05 A | -\$1.73 A |
| 2023 | -\$0.07 A | -\$0.77 A | -\$0.36 E | -\$0.37 E | -\$1.57 E |
| 2024 | | | | | -\$1.50 E |
| 2025 | | | | | -\$1.10 E |

WHAT'S NEW

Second Quarter Fiscal Year 2022 Operational and Financial Results

On March 16th 2023, BriaCell Therapeutics Corp. (NASDAQ: BCTX) reported second quarter fiscal year 2023 financial and operational results in its [Form 10-Q](#) filing with the SEC.

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

BriaCell produced no revenues in the second quarter of fiscal year 2023 and incurred operating expense of (\$4.5) million, yielding a net loss of (\$11.9) million, or (\$0.77) per share. Notably, (\$7.6) million of the loss was attributable to the change in fair value of the warrant liability. Absent this item, net loss was (\$4.5) million or (\$0.29) per share.

For the second quarter ending January 31, 2023 versus the same ending January 31, 2022:¹

- Research & development expense was \$3.1 million, up 76% from \$1.7 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;
- General & administrative expenses totaled \$1.4 million, down 35% from \$2.2 million, due to a reduction in share-based compensation;
- Financial loss totaled (\$7.4) million with a negative change in warrant liability related to an increase in the stock price over the measurement period and a small foreign exchange loss partially offset by \$241,000 in interest income;
- Net loss totaled (\$11.9) million vs. (\$3.9) million, or (\$0.24) and (\$0.30), respectively. Absent the charge for warrant liability, net loss was (\$4.5) million or (\$0.29) per share.

As of January 31, 2023, cash and equivalents totaled \$33.5 million compared to \$41.0 million at the end of the fiscal year last July. Cash burn year to date totaled \$7.5 million. Financing cash flows were minimal and related to a small share buyback.

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.

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.

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 circulating 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.

Asset Spin Out

In a March 30 [press release](#), BriaCell indicated its intention to spin out certain preclinical assets into a newly created company. The assets would include Bria-TILsRx and PKC δ inhibitors for multiple indications. 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 SpinCo share, which will make up one-third of the ownership of SpinCo. The SpinCo assets include the PKC δ inhibitors, which have been shown to be effective treatments for several animal models of cancer and Bria-TILsRx which are being developed as immunotherapies for cancer. The former (PKC δ inhibitors) are highly selective and may be developed as candidates for multiple disease indications and multiple tumors. The latter (Bria-TILsRx) are multi-specific binding reagents designed to act as potent immune cell activators and/or immune checkpoint inhibitors. They are expected to selectively target and destroy cancer cells without harming normal (non-cancerous) cells. The use of Bria-TILsRx may reduce severe side effects for the treated cancer patients compared to alternative therapies.

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.² The interim readout also identified a

² Patients enrolled in the trial had failed an average of five other treatments prior to enrolling in the BriaCell study.

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.

We speak with BriaCell CEO, Dr. Williams about the recently released interim data and what it means for the future development of Bria-IMT.

Exhibit I – Dr. Williams Discusses Bria-IMT Interim Data³



A Series of Discussions with BriaCell CEO Dr. Bill Williams

- [BriaCell Survival Data](#)
- [An Interim Look at Bria-IMT](#)
- [Impressive Survival From First Cohort of Patients](#)
- [What's Next for BriaCell?](#)
- [Fireside Chat: Investor sentiment, cash levels and using AI in drug development](#)

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.

CEO Letter to Shareholders

BriaCell's CEO shares his optimism on the potential for Bria-IMT in a [letter](#) to shareholders in late January 2023. He highlights BriaCell's accomplishments in the lead Bria-IMT program and the recent feedback from the FDA regarding pivotal trial design. The FDA has agreed that the primary endpoint should be survival improvement com-

³ Source: BriaCell Interview Screen Capture

pared with the alternative of the physician's choice of treatment. Final details of the pivotal study protocol are being finalized. In parallel with the regulatory work, BriaCell is also producing batches of Bria-IMT and testing capabilities required for larger scale patient dosing. The Fast Track status that was granted to the company is allowing for this ongoing interaction with the agency and is expected to accelerate protocol review and feedback timelines. BriaCell may be able to initiate patient dosing in a pivotal trial in 2Q:23.

Illegal Trading of Public Securities

BriaCell believes that certain individuals and/or companies may have engaged in manipulative and/or suspected illegal trading practices that may have artificially depressed its share price. As a result, BriaCell is [implementing](#) a plan to address this issue which may include legal action. The company believes this action is necessary in order to protect the interests of stakeholders.

Bria-OTS Clinical Study Status

The Bria-OTS program is also moving ahead and patients in a Phase I/IIa clinical study may be dosed in 2Q:23. Bria-OTS may be able to treat almost all breast cancer patients as the cells correspond with multiple human leukocyte antigen (HLA) types. Another benefit of Bria-OTS is that it is OTS, or off the shelf, and does not require autologous cells to match to the patient. This provides multiple benefits including lower cost of manufacture and quicker availability for patients who require the treatment.

Patent Issued

BriaCell [announced](#) that it was issued a new patent that protects its Bria-OTS technology for breast and other cancers until 2040. The patent, entitled [Whole-cell cancer vaccines and methods for selection thereof](#), was issued and published in January 2023 as patent number 11,559,574. The invention provides a modified human cancer cell comprising a recombinant polynucleotide encoding an allele of a human leukocyte antigen gene. It also provides methods for selecting a whole-cell cancer vaccine for a subject having cancer and methods of treating cancer using whole-cell cancer vaccines. Additionally, the approach provides a method of determining the HER2 status of a cell.

San Antonio Breast Cancer Symposium

BriaCell attended the 2022 [San Antonio Breast Cancer Symposium](#) in early December and presented several posters summarizing data from its Phase I/IIa clinical study of Bria-IMT and reviews preclinical efforts for the company's next generation of products. In addition to details on individual patient performance in the trial and a summary of safety data, BriaCell also shared details on quality of life for patients examined indicators of clinical response including HLA matching and delayed type hypersensitivity.

Summary

BriaCell has been busy running its Bria-IMT trial and preparing Bria-OTS for the clinic. A plethora of posters have been presented at a variety of conferences, including most recently at AACR where updated survival data and potential new biomarkers for success were identified. The strong survival data is a positive and is well-aligned with the FDA-agreed primary endpoint for the upcoming pivotal trial for Bria-IMT in these patients. Further interaction with the FDA is expected which will nail down the final trial design for Bria-IMT and with the launch of Bria-OTS into the clinic. We maintain our valuation of \$15.00 per share.

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement⁴

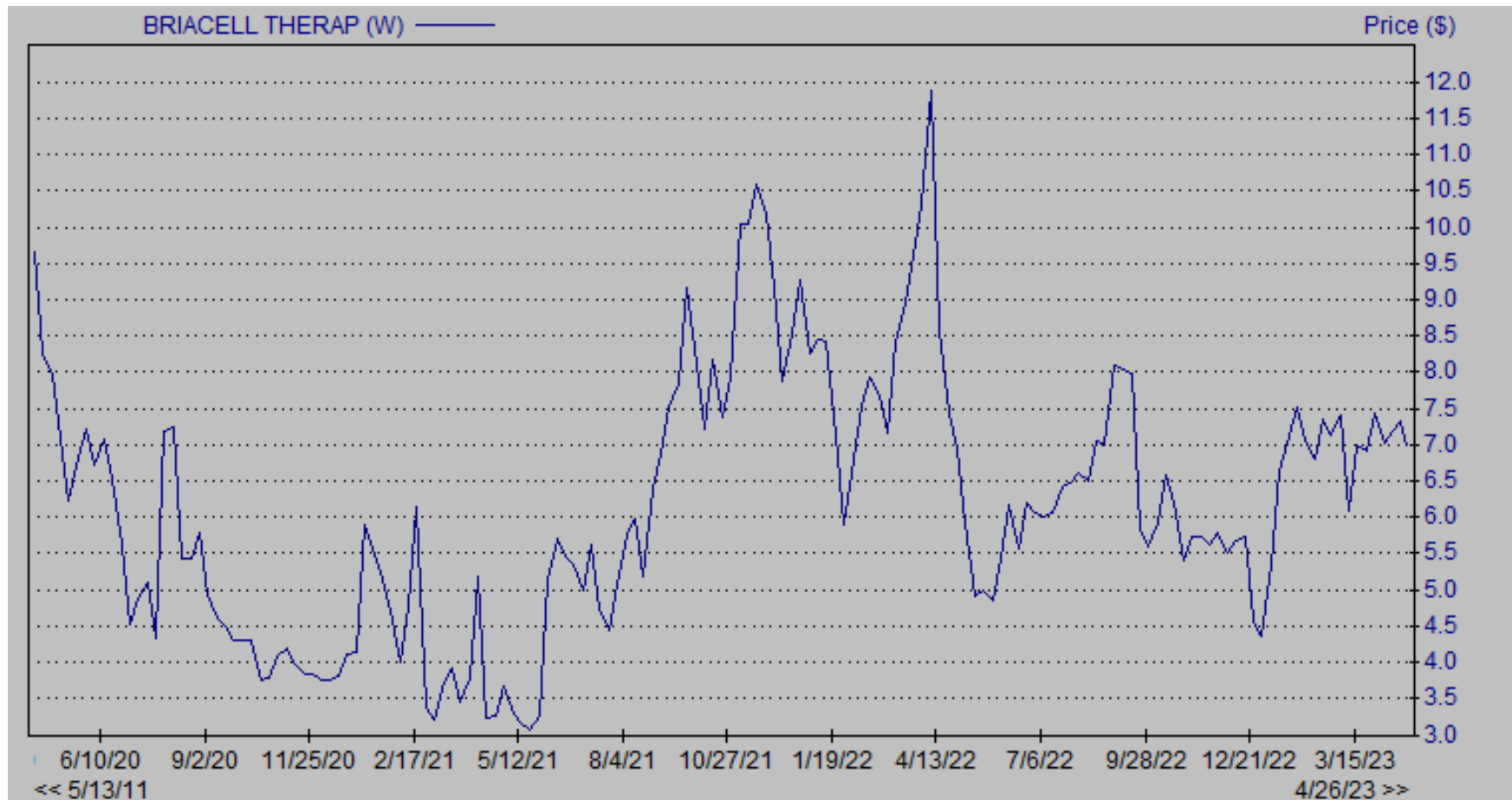
| BriaCell Therapeutics Corp | 2022 A | Q1 A | Q2 A | Q3 E | Q4 E | 2023 E | 2024 E | 2025 E |
|-------------------------------|-------------------|------------------|-------------------|------------------|------------------|-------------------|-------------------|-------------------|
| Total Revenues (\$USD) | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>YOY Growth</i> | | | | | | | | |
| Research & Development | \$8,021 | \$3,255 | \$3,053 | \$3,550 | \$3,800 | \$13,659 | \$18,945 | \$12,250 |
| General & Administrative | \$7,267 | \$2,148 | \$1,433 | \$1,985 | \$2,020 | \$7,586 | \$8,200 | \$8,550 |
| Share Based Compensation | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Income from operations | (\$15,289) | (\$5,403) | (\$4,486) | (\$5,535) | (\$5,820) | (\$21,244) | (\$27,145) | (\$20,800) |
| <i>Operating Margin</i> | | | | | | | | |
| Other Items | (\$11,550) | \$4,297 | (\$7,395) | \$0 | \$0 | (\$3,099) | \$0 | \$0 |
| Fx Translation | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| Pre-Tax Income | (\$26,839) | (\$1,107) | (\$11,882) | (\$5,535) | (\$5,820) | (\$24,343) | (\$27,145) | (\$20,800) |
| Provision for Income Tax | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 | \$0 |
| <i>Tax Rate</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> | <i>0.0%</i> |
| Net Income | (\$26,839) | (\$1,107) | (\$11,882) | (\$5,535) | (\$5,820) | (\$24,343) | (\$27,145) | (\$20,800) |
| <i>Net Margin</i> | | | | | | | | |
| Reported EPS | (\$1.73) | (\$0.07) | (\$0.77) | (\$0.36) | (\$0.37) | (\$1.57) | (\$1.50) | (\$1.10) |
| <i>YOY Growth</i> | | | | | | | | |
| Basic Shares Outstanding | 15,494 | 15,518 | 15,518 | 15,525 | 15,533 | 15,524 | 18,100 | 18,900 |

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

⁴ Financial statement information presents data as originally reported.

HISTORICAL STOCK PRICE

BriaCell Therapeutics Corp. – Share Price Chart⁵



⁵ Source: Zacks Research System

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