Zacks Small-Cap Research
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BriaCell Therapeutics Corp. (BCTX: NASDAQ)

SITC Poster Presentation

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 (11/18/2022)	$5.64
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	**12.47**
52-Week Low	**4.06**
One-Year Return (%)	**-44.2**
Beta	**1.39**
Average Daily Volume (sh)	**387,235**
Shares Outstanding (mil)	**15.5**
Market Capitalization ($mil)	**87.4**
Short Interest Ratio (days)	**4.1**
Institutional Ownership (%)	**16.4**
Insider Ownership (%)	**22.1**
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 2022 Estimate	**N/A**
P/E using 2023 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)
2021	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023					$0.0 E
2024					$0.0 E

Earnings per Share

	Q1 (Oct)	Q2 (Jan)	Q3 (Apr)	Q4 (Jul)	Year (Jul)
2021	-$0.54 A	-$0.30 A	$0.63 A	-$0.24 A	-$0.09 A
2022	-$0.16 A	-$0.24 A	-$0.32 A	-$1.05 A	-$1.73 A
2023					-$1.28 E
2024					-$1.36 E

*FY:21 EPS does not sum to annual due to large increase in share count in 2H:21.

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WHAT'S NEW

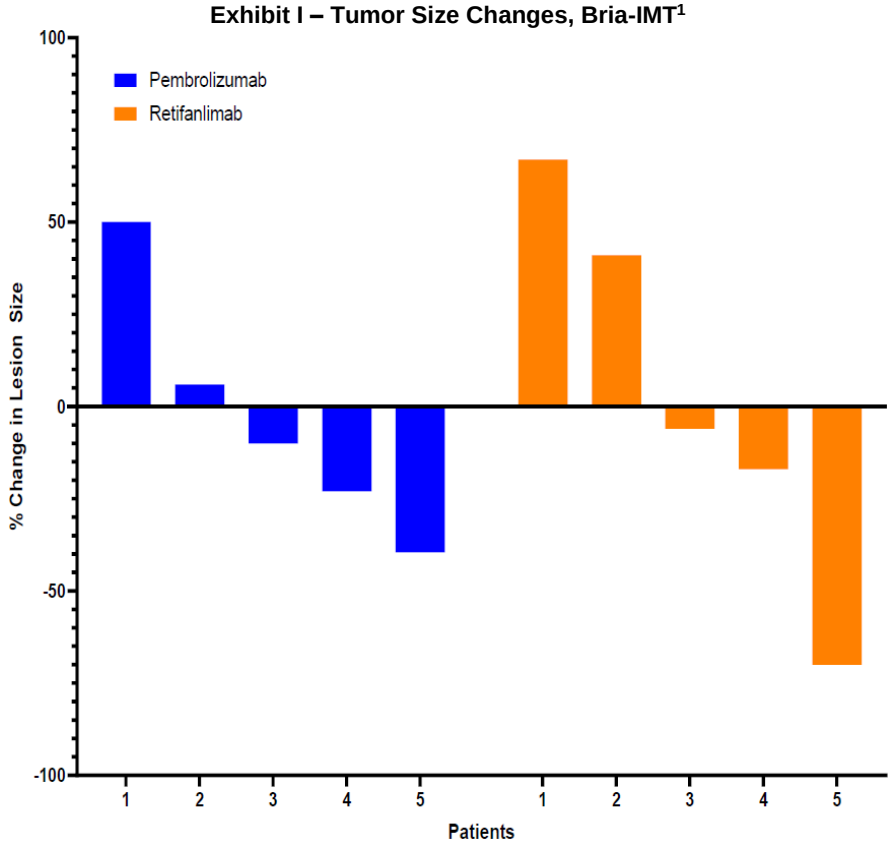
Bria-IMT Breast Cancer Efficacy Data

BriaCell attended the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting and presented data from its Phase I/IIa clinical study of Bria-IMT and described the process for developing its next generation of cellular immunotherapy. The title of the poster is "*An off the shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors*." The related study generating the data shared in the poster is evaluating the safety and efficacy of the treatment in patients with metastatic or locally recurrent breast cancer. Bria-IMT is being administered in combination with PD-1 inhibitor retifanlimab and has demonstrated favorable results. The poster reviews the clinical performance of Bria-IMT, explains the process for producing the next generation of cellular immunotherapy and discusses its dual mechanism of action.

We discuss this poster in a video interview with CEO Dr. Williams here: SITC Poster Presentation

The clinical trial for Bria-IMT, also designated SV-BR-1-GM, has enrolled 33 subjects in monotherapy study and 21 subjects in combination therapy with a PD-1 inhibitor. Patients that responded best in terms of disease control to both the monotherapy and combination therapy shared human leukocyte antigen (HLA) allele matches with the cell line used. For most subjects, the drug regimen effectively reduced tumor size. In the following exhibit, we show change in tumor size for patients in the combination study with both pembrolizumab (in blue) and with retifanlimab (orange).

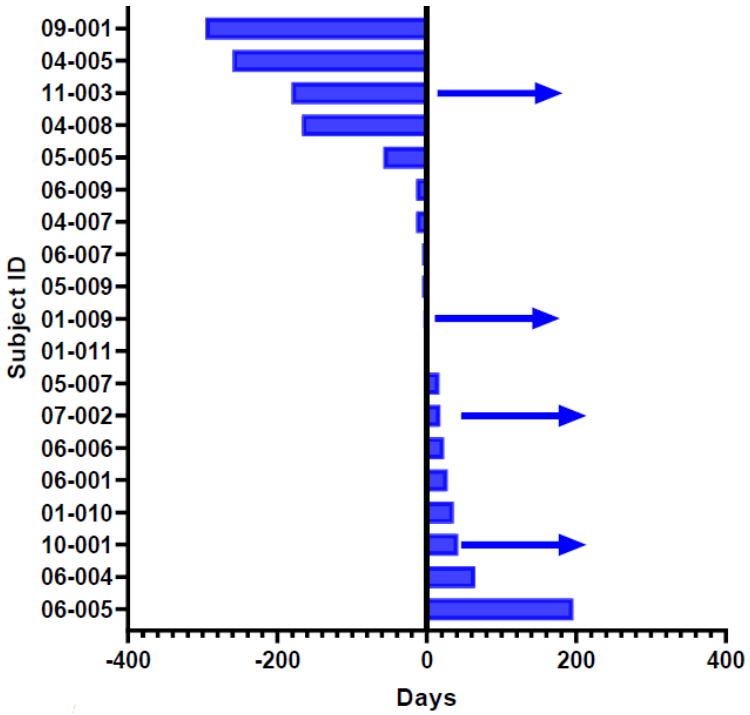
Exhibit I – Tumor Size Changes, Bria-IMT[1]



For later line patients that have failed other lines of therapy, it is difficult to determine the effectiveness of a new approach. To partially address this shortcoming, BriaCell compared the length of time on the Bria-IMT combination with the length of time on their prior regimen. Generally, time on therapy becomes shorter and shorter as the patient declines; however, many patients demonstrated longer progression free survival with Bria-IMT and a PD-1 inhibitor as compared to their prior regimen.

[1] Lopez-Lago, M., *et al.* An off-the-shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors. BriaCell SITC annual meeting, Boston. November 8-12, 2022.

Exhibit II – PFS Compared with Prior Therapy[2]

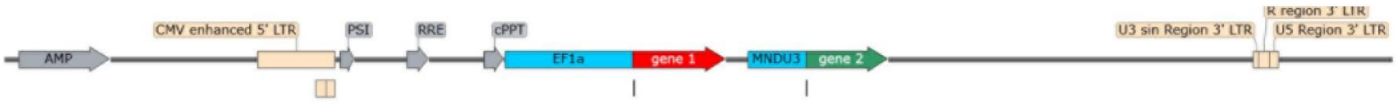


The poster provides background information on BriaCell's next generation cellular immunotherapy which offers two complimentary mechanisms of action: cross-presentation of cancer cell antigens and direct T cell activation. To prepare the therapy, the research group collected cancer cell lines in breast, prostate, melanoma and lung tissue and modified them to provide enhanced immunogenicity. Two primary genetic modifications were made:

- Expression of costimulatory molecules (CD80, CD86, 4-1BB-L) and immunomodulatory cytokines (GM-CSF, IFNa, IL-12 and IL-7).
  - The purpose of this modification is to enhance the cell's antigen presentation properties.
- Expression of an extended repertoire of HLA alleles to generate semi-allogeneic cell lines that will match the whole population at least at one HLA allele.
  - The purpose of this approach is to force the host immune response to recognize tumor-associated antigens in the context of allogeneic MHC-I or II molecules or in proximity of strong non-self anti-gens.

The modifications are expected to enable a set of cell lines that will match over 99% of the patient population for at least one HLA allele. Lentiviral vectors are used to deliver two different genes from independent promoters that will produce the Bria-OTS products. This product will express multiple cytokines and co-stimulatory molecules that can heat up the tumor environment and activate the body's immune system.

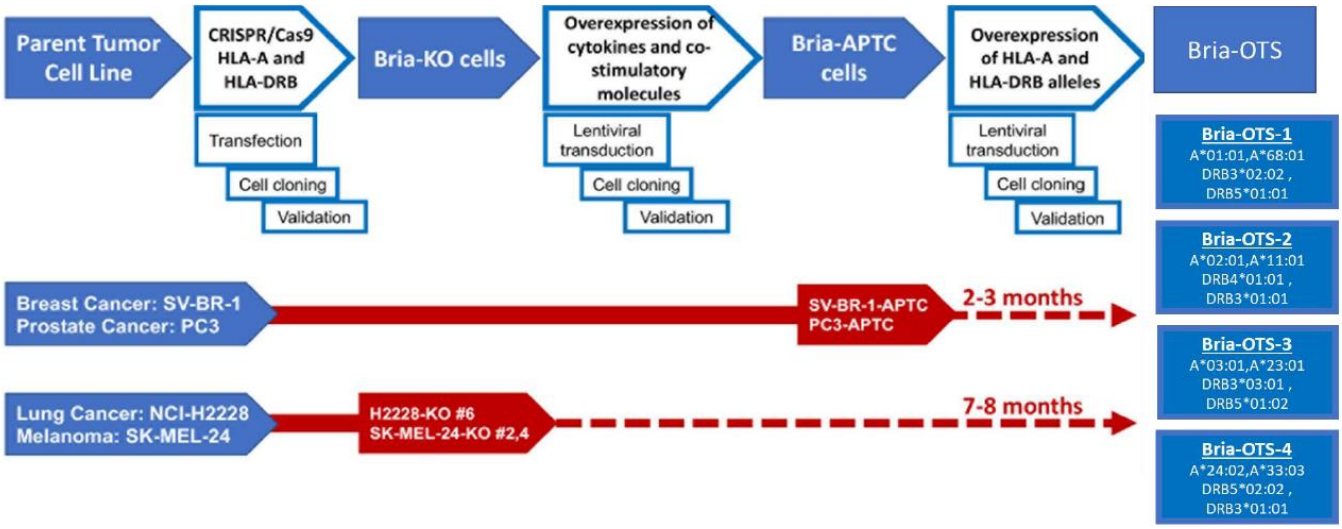
Exhibit III – Lentiviral Vector Delivering New Genes[3]



The following exhibit shows the process of developing BriaCell's next generation of cellular immunotherapy. Gene editing is used to knock out unwanted genes, then a lentiviral vector is used to insert the gene sequence for desired cytokines and co-stimulatory molecules. The result of the modifications is Bria-OTS, a cellular immunotherapy that can match with almost all cancer patients' HLA types.

[2] Lopez-Lago, M., *et al.* An off-the-shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors. BriaCell SITC annual meeting, Boston. November 8-12, 2022.
[3] Lopez-Lago, M., *et al.* An off-the-shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors. BriaCell SITC annual meeting, Boston. November 8-12, 2022.

Exhibit IV – Process for Developing Bria-OTS[4]



BriaCell's next generation of cellular immunotherapy is expected to address a broader population that should include near 99% of HLA phenotypes. Bria-OTS can be administered after HLA genotypying and does not require additional personalization. With the high degree of matching, Bria-OTS can be an off-the-shelf product that provides a dual mechanism of action with features of both cancer cells and dendritic cells that are expected to enhance the immune response in cancer patients. Bria-OTS can further be a precision therapy with improved safety relative to existing chemotherapy and hormone-based products.

See our interviews with CEO Dr. Bill Williams:

- Introduction to Bria-IMT
- SITC Poster Presentation Summary

Summary

BriaCell's poster at SITC updates stakeholders on the most recent performance of the Phase II clinical trial in metastatic or locally recurrent breast cancer. We are also introduced to the process used for the next generation of cellular immunotherapy that provides a dual mechanism of action employing co-stimulatory molecules and expression of additional alleles that allow for a broader population to be addressed.

[4] Lopez-Lago, M., *et al.* An off-the-shelf personalized cellular approach to immunotherapy for the treatment of advanced solid tumors. BriaCell SITC annual meeting, Boston. November 8-12, 2022.

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement[5]

BriaCell Therapeutics Corp	2021 A	Q1 A	Q2 A	Q3 A	Q4 A	2022 A	2023 E	2024 E
Total Revenues ($USD)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Research & Development	$1,315	$876	$1,734	$2,543	$2,869	$8,021	$14,852	$18,945
General & Administrative	$3,690	$891	$2,199	$2,302	$1,875	$7,267	$4,100	$4,500
Share Based Compensation	$1,968	$518	$0	$0	$0	$0	$1,200	$1,200
Income from operations	($6,973)	($2,285)	($3,932)	($4,846)	($4,744)	($15,289)	($20,152)	($24,645)
Other Items	$6,545	($101)	$67	$6	($11,522)	($11,550)	$0	$0
Pre-Tax Income	($428)	($2,386)	($3,865)	($4,839)	($16,266)	($26,839)	($20,152)	($24,645)
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	**($428)**	**($2,386)**	**($3,865)**	**($4,839)**	**($16,266)**	**($26,839)**	**($20,152)**	**($24,645)**
Reported EPS	**($0.09)**	**($0.16)**	**($0.24)**	**($0.32)**	**($1.05)**	**($1.73)**	**($1.28)**	**($1.36)**
Basic Shares Outstanding	4,520	15,239	15,789	15,359	15,518	15,494	15,750	18,100

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

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

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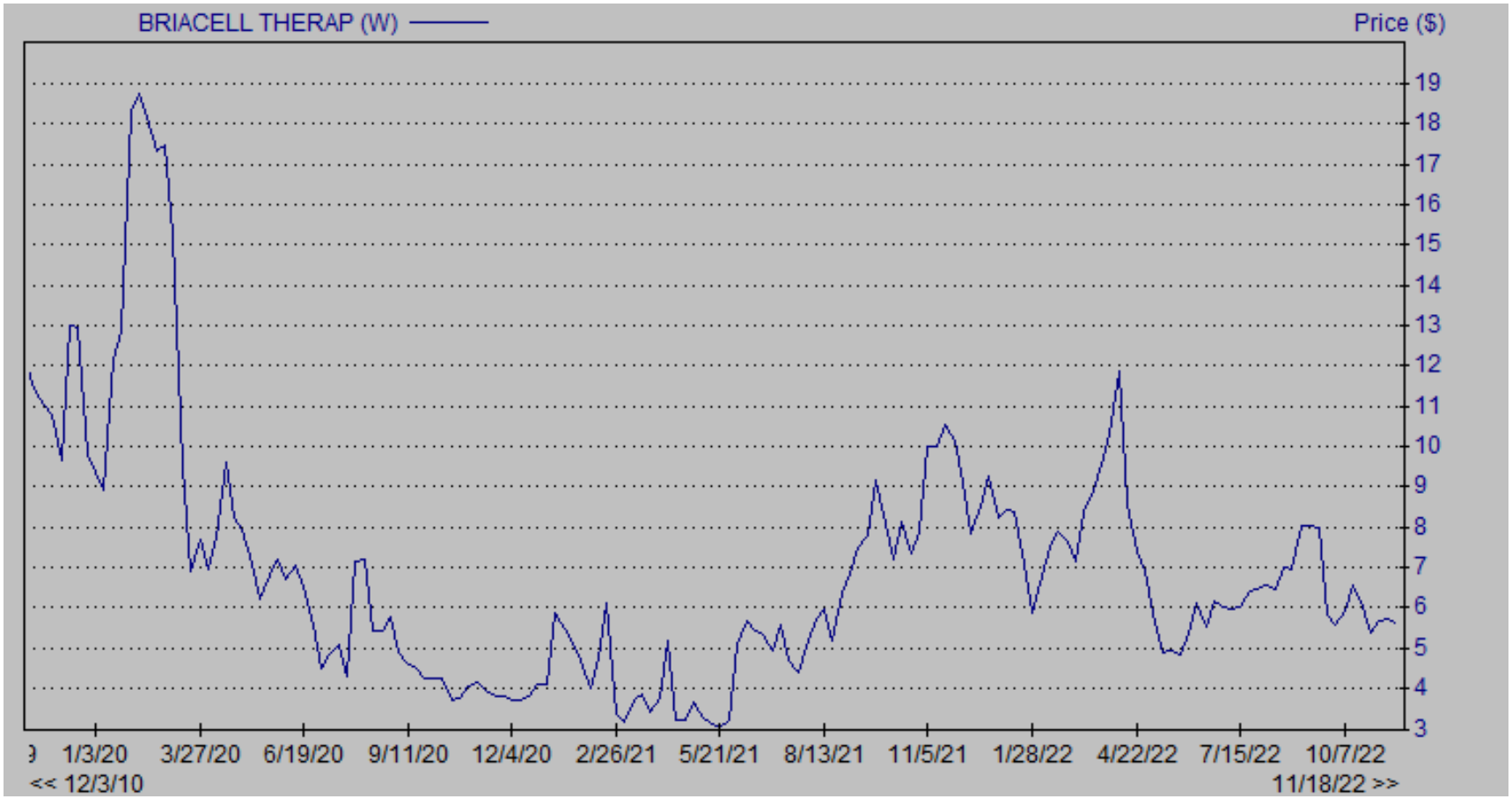
HISTORICAL STOCK PRICE

BriaCell Therapeutics Corp. – Share Price Chart[6]



[6] Source: Zacks Research System

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