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

82% Survival Benefit

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 (3/8/2023)	$6.98
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	**12.09**
52-Week Low	**4.06**
One-Year Return (%)	**-3.7**
Beta	**1.65**
Average Daily Volume (sh)	**224,688**
Shares Outstanding (mil)	**15.5**
Market Capitalization ($mil)	**108.2**
Short Interest Ratio (days)	**6.1**
Institutional Ownership (%)	**17.3**
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 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)
2022	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2023	$0.0 A	$0.0 E	$0.0 E	$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	-$0.34 E	-$0.36 E	-$0.37 E	-$1.14 E
2024					-$1.50 E
2025					-$1.10 E

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WHAT'S NEW

Bria-IMT Breast Cancer Survival Benefit

BriaCell Therapeutics Corp. (NASDAQ: BCTX) reported impressive survival data in an interim look at the ongoing Phase II study in Bria-IMT in advanced metastatic breast cancer patients. The goal of the interim look is to show stakeholders that Bria-IMT continues to extend its survival benefit as the trial progresses. Other company updates since our last report in December include a new patent, feedback from the FDA in an End-of-Phase II meeting among other highlights.

Bria-IMT Interim Update

In the latest update from the Phase II trial evaluating Bria-IMT in advanced metastatic breast cancer patients, an interim update 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 are reported as still alive.

Briacell enrolled eleven subjects in first cohorts in 2021 and 2022 and reports in late February 2023 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.[1] 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.

An additional nine patients have been screened or enrolled in the study, adding to the twelve announced in December 2022. We expect to see further interim updates from the Phase II trial in the future. In the meantime, 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 Data[2]



[1] Patients enrolled in the trial had failed an average of five other treatments prior to enrolling in the BriaCell study.
[2] Source: BriaCell Interview Screen Capture

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 compared 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 cancer patients and the interest of its shareholders.

The Bria-OTS program is also moving ahead and patients in a Phase I/IIa clinical study may be dosed in 1H: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.

BriaCell presented three posters at SABCS[3] which we list below:

1. Allogeneic, Antigen-Presenting, GM-CSF-secreting, SV-BR-1-GM Whole Cell Therapeutic Vaccine in Advanced Metastatic Breast Cancer
2. Decreases in Circulating Tumor Associated Cells Predict PFS and OS in a Pooled Analysis of Phase I Clinical Trials Using SV BR 1 GM Therapy with or without Immune Check Point Inhibitors in Metastatic Breast Cancer Patients
3. Turning tumor cells into antigen presenting cells for cancer immunotherapy

Summary

Following multiple updates in late 2022, BriaCell provides additional data on the survival benefit for Bria-IMT patients in advanced metastatic breast cancer. We have an opportunity to speak with Dr. Williams about the details of the new data release and where things are going in the future. 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. We maintain our valuation of $15.00 per share.

[3] Abstracts and authors can be found here.

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement[4]

BriaCell Therapeutics Corp	2022 A	Q1 A	Q2 E	Q3 E	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	$3,300	$3,550	$3,800	$13,905	$18,945	$12,250
General & Administrative	$7,267	$2,148	$1,925	$1,985	$2,020	$8,078	$8,200	$8,550
Share Based Compensation	$0	$0	$0	$0	$0	$0	$0	$0
Income from operations	($15,289)	($5,403)	($5,225)	($5,535)	($5,820)	($21,983)	($27,145)	($20,800)
Operating Margin								
Other Items	($11,550)	$4,297	$0	$0	$0	$4,297	$0	$0
Fx Translation	$0	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($26,839)	($1,107)	($5,225)	($5,535)	($5,820)	($17,687)	($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)**	**($5,225)**	**($5,535)**	**($5,820)**	**($17,687)**	**($27,145)**	**($20,800)**
Net Margin								
Reported EPS	**($1.73)**	**($0.07)**	**($0.34)**	**($0.36)**	**($0.37)**	**($1.14)**	**($1.50)**	**($1.10)**
YOY Growth								
Basic Shares Outstanding	15,494	15,518	15,520	15,525	15,533	15,524	18,100	18,900

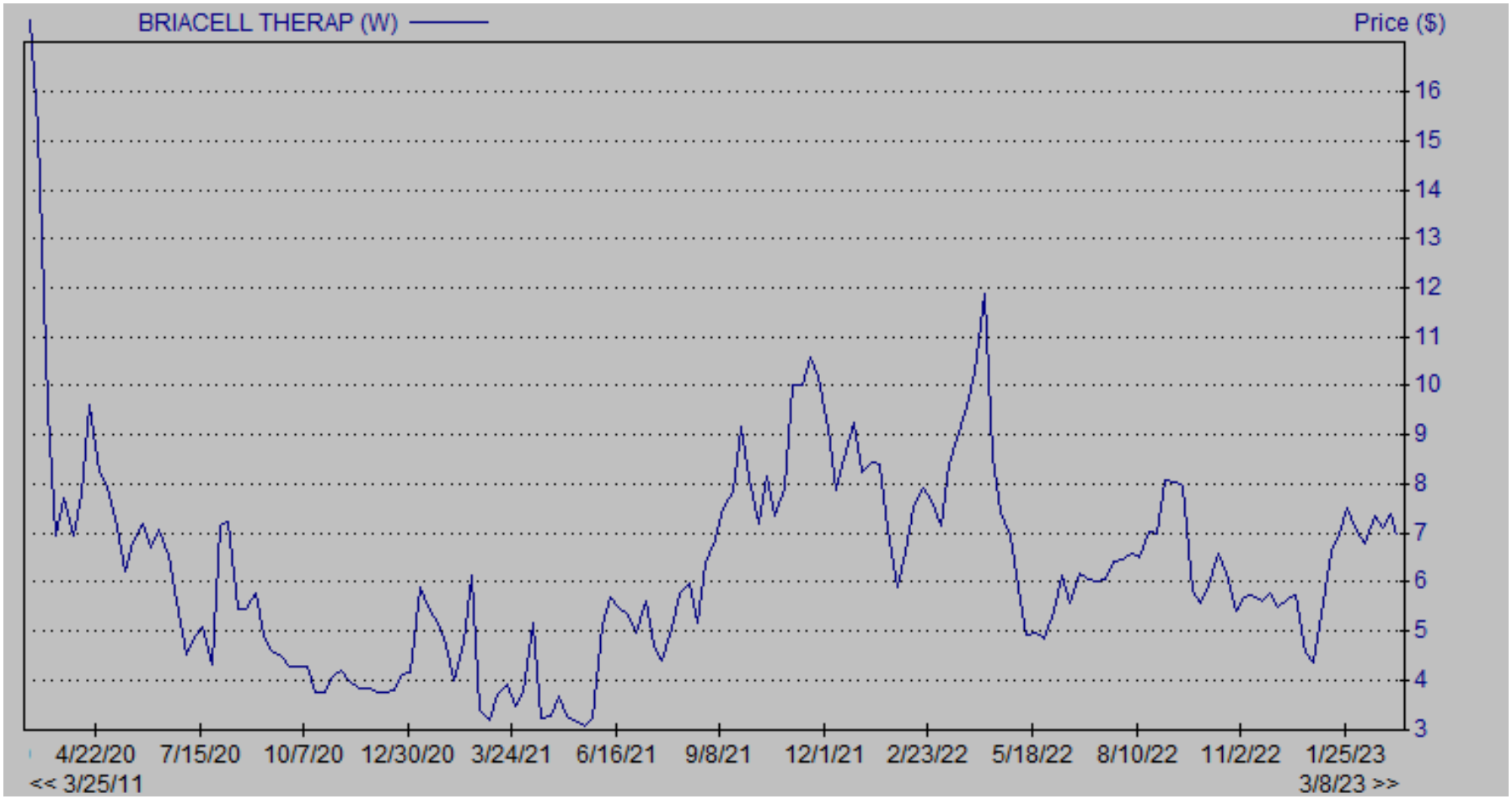
Source: Company Filing // Zacks Investment Research, Inc. Estimates

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

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HISTORICAL STOCK PRICE

BriaCell Therapeutics Corp. – Share Price Chart[5]



[5] Source: Zacks Research System

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