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November 1, 2023
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BriaCell Therapeutics Corp. (BCTX: NASDAQ)

BCTX: Year in Review

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 (10/31/2023)	$4.25
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	**8.10**
52-Week Low	**3.67**
One-Year Return (%)	**-22.7**
Beta	**1.67**
Average Daily Volume (sh)	**92,454**
Shares Outstanding (mil)	**16.0**
Market Capitalization ($mil)	**68.0**
Short Interest Ratio (days)	**14.7**
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 A	$0.0 A
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	-$0.16 A	-$1.30 A
2024					-$1.50 E
2025					-$1.10 E

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WHAT'S NEW

Fiscal Year 2023 Operational and Financial Results

On October 25th 2023, BriaCell Therapeutics Corp. (NASDAQ: BCTX) reported fiscal year 2023 financial and operational results in the filing of Form 10-K. Results were presented for the fiscal year ending July 31st, 2023. Since our previous update in early July, BriaCell has made substantial progress in its Bria-IMT program identifying partners for the study, initiating it and forming a medical advisory board to advance the candidate. A special meeting was held to obtain approval to spin out BriaPro Therapeutics which was subsequently awarded to shareholders. Stakeholder interaction was also a priority with a key opinion leader (KOL) event and planned participation in the Society for the Immunotherapy of Cancer (SITC) and San Antonio Breast Cancer (SABC) conferences. Finally, BriaCell received a National Cancer Institute (NCI) grant to advance Bria-OTS.

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
- Award of NIDA grant for Bria-OTS – August 2023
- Court approval for and spin-out of BriaPro Therapeutics – August 2023
- Launch of Phase III study of Bria-IMT in advanced metastatic breast cancer – October 2023
- KOL event for metastatic breast cancer and Bria-IMT – October 2023

BriaCell produced no revenues in FY:23 and incurred operating expense of ($23.3) million, yielding a net loss of ($20.3) million, or ($1.30) per share. Cash burn was ($23.7) million. Below we compare results for fiscal year 2023 with fiscal year 2022 both of which ended July 31st.

- Research & development expense was $15.3 million, up 91% from $8.0 million, with increases in every category of spending due to increased clinical activity for the Phase I/II Bria-IMT trial. Categories seeing the largest increases were clinical trial expense, including trial site and drug cost, increased wages and salaries, and greater share-based compensation. Spending on preclinical projects and Chemistry, Manufacturing and Control (CMC) was also significantly higher;
- General & administrative expenses totaled $7.9 million, rising 9% from $7.3 million, due to higher insurance premiums, professional fees and salaries. These were offset by a decrease in share-based compensation expenses;
- Financial income totaled $3.0 million with a positive change in warrant liability related to a decrease in the stock price over the measurement period. This compares to a loss of ($11.6) million;
- Net loss totaled ($20.3) million vs. ($26.8) million, which was a loss per share of ($1.30) and ($1.73).

As of July 31st, 2023, cash and equivalents totaled $21.3 million compared to $41.0 million at the end of the fiscal year last July. Cash burn year to date totaled ($23.7) million. Financing cash flows were about $4 million related to a fourth quarter issuance of shares along with a minor impact from a small share and warrant buyback and proceeds from warrant exercise.

BriaCell KOL Event

BriaCell along with LifeSci Advisors organized a key opinion leader (KOL) event featuring BriaCell executives and oncology experts who have contributed to the Phase II Bria-IMT clinical trial. Following a presentation describing Bria-IMT by BriaCell CEO, Dr. William Williams, Chief Medical Officer Dr. Giuseppe Del Priore introduced the KOL speakers Drs. Adam Brufsky and Saranya Chumsri. Dr. Brufsky is an oncologist at University of Pittsburgh School of Medicine among other roles in the medical oncology space while Dr. Chumsri who is the Mayo Clinic Enterprise Research Breast Disease Group Chair among other roles.

Dr. Brufsky reviewed the National Comprehensive Cancer Network (NCCN) guidelines for recurrent unresectable (Stage IV) metastatic breast cancer. In HR+/- and HER2+ patients, treatment begins with pertuzumab, trastuzumab and docetaxel or paclitaxel. Other agents are added to trastuzumab in second and third line, while in fourth line there are a wide variety of approaches including investigational drugs. Dr. Brufsky reviewed common treatment regimens including antibody-drug conjugates (ADCs) trastuzumab deruxtecan (T-DXd) and trastuzumab emtansine (T-DM1). These drugs also have side effect profiles that include pneumonitis and left ventricular dysfunction, which can be fatal. Furthermore, many patients will become resistant to therapy which leaves few options for sick patients. Despite the advances that have been made, Dr. Brufsky stressed the unmet need for patients that do progress following use of approved therapies.

Dr. Chumsri discussed the development of Bria-IMT and shared her experience using the vaccine with breast cancer patients. As we have discussed in earlier reports, Bria-IMT's predecessor, SV-BR-1, was taken from a breast cell cancer line from a chest wall metastasis of grade 2 metastatic breast cancer. SV-BR-1 was then transfected with the CSF2 gene to produce granulocyte-macrophage colony-stimulating factor (GM-CSF) OR Bria-IMT. The product is frozen to preserve stability and thawed at the clinical site where it is injected intradermally in patients to elicit an immune response. Bria-IMT is used in combination with cyclophosphamide and post-treatment micro-dose interferon-α. BriaCell's follow-up vaccine is an off-the-shelf candidate and does not require autologous input. She also highlighted the development of Bria-OTS, the off-the-shelf version of the candidate is expected to be effective in a higher proportion of mBC patients compared with Bria-IMT.

Dr. Chumsri reviewed studies conducted to investigate Bria-IMT that demonstrated the ability to reduce tumor size. The effect was especially pronounced when there were multiple human leukocyte antigen (HLA) matches. Clinical studies demonstrated proof of concept and that the agent was well-tolerated by patients. She noted that responsive patients show a delayed type hypersensitivity (DTH) reaction on the skin. In the next segment of her talk, Dr. Chumsri reviewed many of the other studies that we have described in previous reports over the last couple years.

The final section of the event included related highlights presented by the KOLs and BriaCell executives and an opportunity for audience questions and panel answers. Topics included the opportunity for Bria-IMT to later move to earlier lines of therapy, regulatory considerations related to trial design and risk benefit and

Launch of Phase III Pivotal Trial for Bria-IMT

BriaCell announced the initiation of the Phase III study of Bria-IMT in advanced metastatic breast cancer on October 3rd. The study expects to enroll 354 subjects in two cohorts in a 1:1 ratio. To gather additional information on the Bria-IMT regimen alone, 50 patients will be enrolled in Bria-IMT monotherapy and will be eligible to add retifanlimab following the initial post treatment evaluation. Qualifying subjects will have failed at least two approved therapies.

The primary endpoint for the trial is overall survival up to 60 months. Secondary endpoints include progression free survival, clinical benefit rate, overall response rate and quality of life. The arms will include Bria-IMT plus retifanlimab and physician's choice of therapy. Details for the study are listed on clinicaltrials.gov under the designator NCT06072612. Favorable results could support marketing approval for Bria-IMT. Fast Track status is expected to provide frequent and responsive FDA communication during the Phase III study.

BriaCell formed a partnership with New York Cancer & Blood Specialists (NYCBS) to support the Phase III study. NYCBS is a group of leading community cancer centers throughout the state of New York that provides a full range of cancer care services including imaging, therapy and support services. NYCBS will make Bria-IMT available to its patients through participation in the pivotal clinical study.

Advisors Added to BriaCell Boards to Support Bria-IMT Development

An October 25th press release announced that BriaCell had formed a Medical Advisory Board consisting of Massimo Cristofanilli, MD, Sara Hurvitz, MD and Adam Brufsky, MD. These experts in the field of breast cancer are ex-

pected to help guide the progress of Bria-IMT through its pivotal Phase III clinical trial and support the development of a biologic license application (BLA) for submission to the FDA. BriaCell's Chief Medical Officer, Dr. Giuseppe Del Priore, anticipates that the Medical Advisory Board will enable BriaCell to better analyze the science behind the data generated in the trial and support the evolution of the use of the product to help patients in need. Additionally, BriaCell announced the appointment of Charles Sidman, PhD, to its Scientific Advisory Board.

National Cancer Institute Grant

BriaCell's August 16th press release announced that the National Cancer Institute (NCI) awarded a grant to support the development of Bria-OTS. The title of the grant is "An off-the-shelf tumor cell vaccine with HLA-matching alleles for the personalized treatment of advanced solid tumors." Funds will be used to develop BriaCell's personalized off-the-shelf immunotherapy for advanced metastatic breast cancer, prostate cancer, lung cancer and melanoma. The company's CEO, Dr. Williams, noted that the award may open doors for additional non-dilutive funding opportunities.

The grant value was $400,000 to support preclinical work that will support the development of an investigational new drug application (IND). There is a second NCI grant that BriaCell will pursue after achieving certain milestones for $2.5 million that would be used for a Phase I trial if awarded.

Phase III Protocol Development

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 will be Incyte's retifanlimab (Zynyz).[1]

Final details for the pivotal trial have been announced on clinicaltrials.gov and include the number of subjects that will be enrolled (404) and the checkpoint inhibitor that will be used (retifanlimab). 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 and should increase the frequency of meetings between BriaCell and the FDA and open the door for other opportunities including Accelerated Approval, Priority Review and Rolling Review if appropriate.

Exhibit I – BriaCell Pipeline[2]

Therapeutic	Indication	Preclinical	Phase 1	Phase 2	Phase 3	2023 Milestones
Bria-IMT™ CPI Combination	Advanced Metastatic Breast Cancer	Phase 2/3 (Fast Track)				Ongoing Phase 2 Safety & Efficacy Data Pivotal Ph 3 Study Initiated
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

Phase II Clinical Trial for Triple Negative Breast Cancer

On the last day in August, BriaCell accepted a Letter of Intent from Weill Cornell Medicine to begin a Phase II, investigator-initiated clinical study to evaluate Bria-IMT in combination with a checkpoint inhibitor. Checkpoint inhibitors are an emerging treatment option for some patients with triple negative breast cancer (TNBC). TNBC is an aggressive subtype that lacks expression of estrogen/progesterone receptors and HER2. TNBC has been found to be more immunosuppressive and some cases express PD-L1, making immunotherapy a rational treatment approach.

[1] 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.
[2] Source: BriaCell October 2023 Corporate Presentation

The checkpoint inhibitors atezolizumab, pembrolizumab and avelumab are FDA-approved for PD-L1 positive unresectable locally advanced or metastatic TNBC. Combination therapies with checkpoint inhibitors may be even more effective for TNBC compared to single agent therapy. Chemotherapy has been shown to work well with checkpoints as have combinations with other checkpoints such as CTLA-4 inhibitors. Bria-IMT's mechanism of action which stimulates the immune system and activity of CD8 and CD4 positive cells suggests a complementary approach which could work well in the TNBC population. The poor survival outlook for TNBC patients is another reason to pursue this combination therapy with Bria-IMT. It is likely that Keytruda will be used with this study.

The study will begin upon regulatory approval and will receive BriaCell support through technical assistance and contribution of drug. The clinical trial is designed to address the unmet need in high-risk TNBC patients who failed the current standard of care, a neoadjuvant regimen combination with checkpoint inhibitors. The clinical trial is designed to evaluate the safety and efficacy of Bria-IMT and checkpoint inhibitors in early TNBC who completed neoadjuvant therapy and did not achieve pathological complete remission. The primary endpoint is event-free survival above 55% which is the threshold generated in the Keynote 522 study.

Biostrand Antibody Design Progress

BriaCell signed an agreement with Immunoprecise Antibodies' (IPA) subsidiary BioStrand back in November of 2022 to use artificial intelligence to discover and develop anti-cancer antibodies. As of autumn 2023, progress has been made with small molecule development related to the first round of design. Testing of the results are now taking place. BriaCell's former CSO Markus Lacher is working with BioStrand in the drug design effort. Dr. Lacher will combine his proprietary software with BioStrand's process to optimize development.

Spinout of BriaPro Therapeutics Corp.

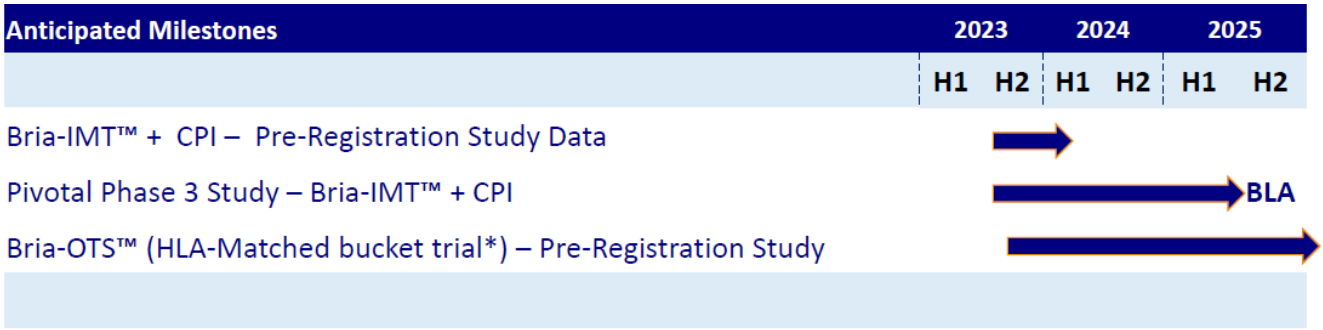
In a March 30, 2023 press release, BriaCell indicated its intention to spin out several preclinical assets. The assets would be part of a new entity majority-owned, controlled and governed by BriaCell, and owned by its shareholders of record who would receive equity shares. In late May BriaCell announced a definitive agreement to spin out this new entity to be called BriaPro Therapeutics Corp. In mid-August, a special meeting was held to vote on the transaction, which was approved. Three resolutions were passed including the arrangement to spin out the assets into a new company, the approval of the BriaPro option plan and the grant of stock options to stakeholders. Court approval was granted a few days later by the Supreme Court of British Columbia with an effective date and closing as of August 31st. Under the terms of the arrangement, for each BriaCell share held immediately prior to closing, BriaCell shareholders receive one common share of BriaPro and one new common share of BriaCell. BriaPro will be an unlisted reporting issuer in Canada. As a result of the Arrangement, there are approximately 47,945,178 SpinCo common shares issued and outstanding. BriaCell beneficially owns or controls approximately 31,963,452 BriaPro common shares, representing 2/3rds of the issued and outstanding BriaPro common shares.

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. Funding for BriaPro is expected to come from grants and potentially private equity or an initial public offering.

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.

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.

Exhibit II – BriaCell Development Timeline[3]



*Bucket trial will include breast cancer, prostate cancer, lung cancer and melanoma

Milestones

- Spin out of BriaPro – August 2023
- Launch Phase III study for Bria-IMT – October 2023
- BriaCell KOL Event – October 2023
- Formation of Medical Advisory Board to guide development of Bria-IMT – October 2023
- Society for the Immunotherapy of Cancer (SITC) meeting – November 2023
- San Antonio Breast Cancer (SABC) Conference – December 2023
- Bria-IMT + checkpoint inhibitor study data – 1H:24
- Completion of Phase III Bria-IMT trial – 2H:25

Summary

BriaCell reports full year results and makes progress in a number of areas with its Bria-IMT and Bria-OTS candidates. The most important achievement is the launch of the pivotal Phase III trial for Bria-IMT which could enroll its first patients any day now. The company has partnered with NYCBS, which has a network of oncologists and clinical sites that will help enroll patients in the trial. With Fast Track authority, BriaCell could begin submitting a BLA in the second half of 2025. A medical advisory board has also been assembled in order to guide ongoing development of Bria-IMT.

BriaCell has created a new company called BriaPro Therapeutics which is now an independent entity which will seek its own funding. Following a shareholder vote and court approval, BriaPro is now a private company 2/3rds owned by BriaCell Corporation and 1/3rd owned by BriaCell shareholders.

Interest in the "Bria-" product line extends outside the corporate walls and includes NIDA which provided a grant for development of Bria-OTS and an investigator-sponsored study of Bria-IMT with Weill Cornell Medicine for a Phase II study in TNBC. With respect to ongoing and completed studies, we expect to see additional new and material data come out which will be presented at the SITC and SABC meetings over the next two months. BriaCell's various value-enhancing activities support our valuation of $15.00 per share.

[3] Source: BriaCell October 2023 Corporate Presentation

PROJECTED FINANCIALS

BriaCell Therapeutics Corp. – Income Statement[4]

BriaCell Therapeutics Corp	2022 A	Q1 A	Q2 A	Q3 A	Q4 A	2023 A	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	$5,167	$15,337	$18,945	$12,250
General & Administrative	$7,267	$2,148	$1,433	$1,816	$2,538	$7,936	$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)	($7,706)	($23,272)	($27,145)	($20,800)
Operating Margin								
Other Items	($11,550)	$4,297	($7,395)	$782	$5,287	$2,970	$0	$0
Fx Translation	$0	$0	$0	$0	$0	$0	$0	$0
Pre-Tax Income	($26,839)	($1,107)	($11,882)	($4,895)	($2,419)	($20,302)	($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)**	**($2,419)**	**($20,302)**	**($27,145)**	**($20,800)**
Net Margin								
Reported EPS	**($1.73)**	**($0.07)**	**($0.77)**	**($0.32)**	**($0.16)**	**($1.30)**	**($1.50)**	**($1.10)**
YOY Growth								
Basic Shares Outstanding	15,494	15,518	15,518	15,518	15,578	15,620	18,100	18,900

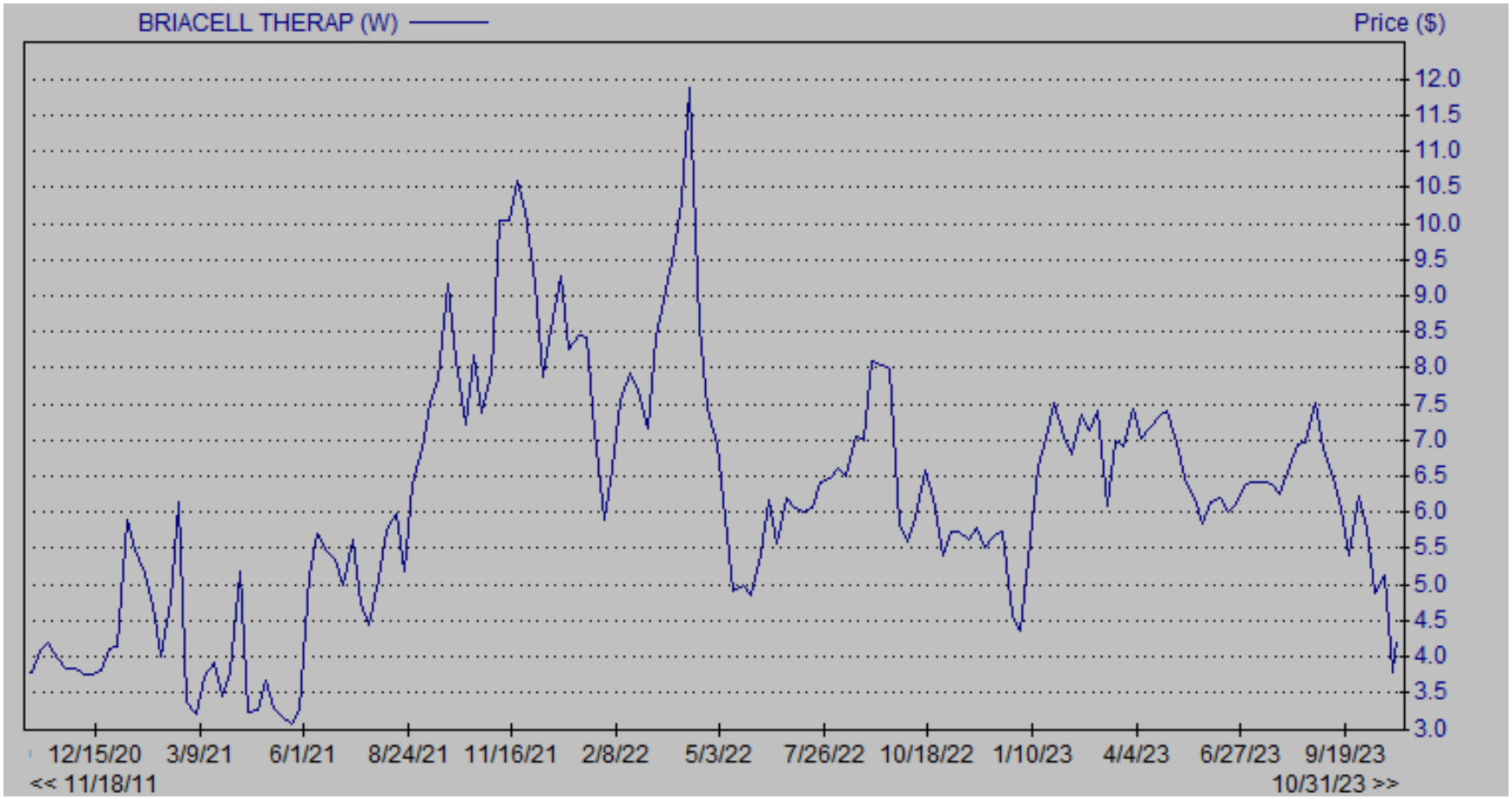
Source: Company Filing // Zacks Investment Research, Inc. Estimates

[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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