UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended July 31, 2024

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from [●] to [●]

Commission File Number: 001-40101

BRIACELL THERAPEUTICS CORP.

(Exact name of registrant as specified in its charter)

British Columbia (State or other jurisdiction of incorporation or organization)	**47-1099599** (I.R.S. Employer Identification No.)
Suite 300 - 235 15th Street **West Vancouver, BC V7T 2X1** (Address of principal executive offices)	**V7T 2X1** (Zip Code)

(604) 921-1810
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Shares, no par value	BCTX	The Nasdaq Stock Market LLC
Warrants to purchase common shares, no par value	BCTXW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐	Non-accelerated filer ☒	Smaller reporting company ☒	Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates based on a closing sale price of $4.12 per share, which was the last sale price of the common shares as of January 31, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was $63,692,423.

As of October 28, 2024, 36,183,161 shares of the registrant's common shares, no par value per share, were issued and outstanding.

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Forward-Looking Statements

This Annual Report on Form 10-K contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements may be identified by such forward-looking terminology as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. Our forward-looking statements are based on a series of expectations, assumptions, estimates and projections about our company, are not guarantees of future results or performance and involve substantial risks and uncertainty. We may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements. Our business and our forward-looking statements involve substantial known and unknown risks and uncertainties, including the risks in the section titled "*Risk Factors*", that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. In addition, you are directed to factors discussed in the "*Business*" section and the "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" section, as well as those discussed elsewhere in this Annual Report on Form 10-K.

All of our forward-looking statements are as of the date of this Annual Report on Form 10-K only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of, or any material adverse change in, one or more of the risk factors or risks and uncertainties referred to in this Annual Report on Form 10-K or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the U.S. Securities and Exchange Commission (the "SEC") could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Annual Report on Form 10-K, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Annual Report on Form 10-K that modify or impact any of the forward-looking statements contained in this Annual Report on Form 10-K will be deemed to modify or supersede such statements in this Annual Report on Form 10-K.

This Annual Report on Form 10-K may include market data and certain industry data and forecasts, which we may obtain from internal company surveys, market research, consultant surveys, publicly available information, reports of governmental agencies and industry publications, articles and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but the accuracy and completeness of such information is not guaranteed. While we believe that such studies, clinical trials and publications are reliable, we have not independently verified market and industry data from third-party sources.

Risk Factor Summary

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled "*Risk Factors*", together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

- We have a history of losses, may incur future losses and may not achieve profitability;
- There is substantial doubt about our ability to continue as a going concern;
- We are a pre-revenue clinical stage company;
- We are developing novel technologies which may not be effective or safe;
- We have an unproven market for our product candidates;
- We are heavily reliant on third-parties to carry out a large portion of our business;
- Pre-clinical studies and initial clinical trials are not necessarily predictive of future results;
- We must obtain additional capital to continue our operations;
- We are highly dependent on our key personnel;
- We may not succeed in completing the development of our products, commercializing our products or generating significant revenues;
- We may not successfully develop, maintain and protect our proprietary products and technologies;
- Changes in legislation and regulations may affect our revenue and profitability;
- If we or our licensees are unable to obtain U.S., Canadian and/or foreign regulatory approval for our product candidates, we will be unable to commercialize our therapeutic candidates;
- Short sellers may be manipulative and may drive down the market price of our common shares;
- Our 2/3rd owned subsidiary BriaPro Therapeutics Corp. ("BriaPro") may not generate revenue as expected;
- Clinical trials involve a lengthy and expensive process with uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results;
- Future issuance of our common shares could dilute the interests of existing shareholders; and
- We have a significant number of options and warrants outstanding, and while these options and warrants are outstanding, it may be more difficult to raise additional equity capital.

PART I

ITEM 1. BUSINESS

BUSINESS

Overview of the Company

BriaCell Therapeutics Corp. ("Briacell" or the "Company") is a clinical-stage biotechnology company that is developing novel immunotherapies to transform cancer care. Immunotherapies have come to the forefront in the fight against cancer as they harness the body's own immune system to recognize and destroy cancer cells. The Company is currently advancing its Bria-IMT™ targeted immunotherapy in combination with an immune check point inhibitor (Retifanlimab) in a pivotal[1] Phase 3 study in metastatic breast cancer. Bria-IMT™ is currently under Fast Track Designation by the U.S. Food and Drug Administration (the "FDA") intended to accelerate the review process of novel treatments that address unmet medical needs. Positive completion of the pivotal study, following review by FDA, could lead to full approval of the Bria-IMT™ immune checkpoint inhibitor combination in metastatic breast cancer. BriaCell reported benchmark-beating patient survival and clinical benefit in metastatic breast cancer with median overall survival of 13.4 months in BriaCell's metastatic breast cancer patients vs. 6.7-9.8 months[2] for similar patients reported in the literature in its Phase 2 study of Bria-IMT™ combination study with retifanlimab at the 2023 San Antonio Breast Cancer Symposium. Additionally, BriaCell reported median overall survival of 15.6 months in Phase 2 Bria-IMT™ study patients treated in combination with immune checkpoint inhibitor in patients treated with the Phase 3 formulation since 2022 (post-COVID). A completed Bria-IMT™ Phase 1 combination study with retifanlimab (an anti-PD1 antibody manufactured by Incyte) confirmed tolerability and early-stage efficacy. BriaCell is also developing personalized off-the-shelf immunotherapies, Bria-OTS™ and Bria-OTS+™, which provides a platform technology to develop personalized off-the-shelf immunotherapies for numerous types of cancer. In September 2024, the Company announced BriaCell has received positive feedback from its Pre-Investigational New Drug Application (Pre-IND) meeting with FDA for Bria-PROS+™ for prostate cancer.

Market

It is estimated by the National Cancer Institute Cancer Facts and Figures that in 2024, approximately 310,720 women will be diagnosed with breast cancer in the United States. That means that every two minutes an American woman is diagnosed with breast cancer and more than 42,250 are projected to die in 2024. Although about 100 times less common than in women, breast cancer also affects men. It is estimated that the lifetime risk of men getting breast cancer is about 1 in 1,000, and the American Cancer Society estimates that approximately 2,790 new cases of invasive male breast cancer will be diagnosed and approximately 530 men will die from breast cancer in 2024.

According to the May 2023 "Global Oncology Trends 2023" report by the IQVIA Institute, the global market for cancer drugs (including immunotherapy drugs) is expected to reach nearly $375 billion by the end of 2027, growing at a compound annual growth rate ("CAGR") of 17% between 2023 and 2027, of which about 20% is expected to be immuno-oncology drugs.

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[1] "Pivotal" is an industry term referring to a Phase 3 clinical study intended to show and confirm the safety and efficacy of a treatment.

[2] Cortes J, et al. Annals of Oncology 2018; Kazmi S, et al. Breast Cancer Res Treat. 2020 Aug 17; O'Shaughnessy J et al. Breast Cancer Res Treat. 2022; Tripathy D, et al. JAMA Oncol. 2022

About 13% percent of women will be diagnosed with breast cancer at some point during their lifetime. In 2024, over 4 million women were living with female breast cancer in the United States. Approximately 83% of cases present as invasive breast cancer. Approximately 6% of new breast cancer diagnoses are Stage IV (metastatic breast cancer ("MBC"), which has already spread to other organs). Twenty to thirty percent of all women diagnosed with breast cancer will develop MBC. Breast cancer can be subdivided based on receptor status - the hormone receptors for estrogen (ER) and progesterone (PR), collectively referred to as hormone receptors (HR), and the Her2/neu growth factor receptor (HER2). Based on the latest SEER statistics, 68% were found to be HR+/HER2−, 10% were triple-negative (HR−/HER2−), 10% were HR+/HER2+, and 4% were HR−/HER2+.[1]

It is estimated that over 150,000 women in the US were living with MBC in 2015[2] and this is projected to increase to over 240,000 by 2030. For those with metastatic disease at diagnosis, their 5-year survival rate is 30%.[1] For patients who develop MBC after initially having localized disease, if they had a good response to treatment (i.e. a disease-free interval of more than 24 months), their survival rate is similar to that of patients with MBC at initial diagnosis, but if their disease-free interval is less than 24 months, their prognosis is worse.[4] We currently propose that Bria-IMT's™ indication will be for the treatment of patients with MBC who have no approved alternative therapies available. Similarly, another study showed that the median overall survival among patients with de novo stage IV MBC was 39.2 months, while for patients with relapsed disease it was 27.2 months.[5] Median progression free survival after first-line therapy is only 9 months and the survival benefit decreases with subsequent lines of therapy.[6] One study showed that of 386 patients with MBC, 374 (97%) received first-line therapy, 254 (66%) received second-line therapy, 175 (45%) received third-line therapy, and 105 (27%) received therapy beyond third-line.[7] More recent data indicates that for patients with MBC who have received 2 or more prior lines of therapy, median survival is 5.9-9.8 months.

[1] See https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2022-2024-breast-cancer-fact-figures-acs.pdf

[2] Mariotto AB, Etzioni R, Hurlbert M, Penberthy L, Mayer M. Estimation of the Number of Women Living with Metastatic Breast Cancer in the United States. Cancer Epidemiol Biomarkers Prev. 2017 Jun;26(6):809-815.

[3] Breast Cancer Facts & Figures 2017-2018. Atlanta: American Cancer Society, Inc. 2017.

[4] Lobbezoo, D. J. A. et al. Prognosis of metastatic breast cancer subtypes: the hormone receptor/HER2-positive subtype is associated with the most favorable outcome. Breast Cancer Res. Treat. 141, 507-514 (2013).

[5] Dawood S, Broglio K, Ensor J, Hortobagyi GN, Giordano SH. Survival differences among women with de novo stage IV and relapsed breast cancer. Ann Oncol. 2010 Nov; 21(11):2169-74.

[6] Bonotto M, Gerratana L, Iacono D, Minisini AM, Rihawi K, Fasola G, Puglisi F. Treatment of Metastatic Breast Cancer in a Real-World Scenario: Is Progression-Free Survival With First Line Predictive of Benefit From Second and Later Lines? Oncologist.

[7] Kotsakis A, Ardavanis A, Koumakis G, Samantas E, Psyrri A, Papadimitriou C. Epidemiological characteristics, clinical outcomes and management patterns of metastatic breast cancer patients in routine clinical care settings of Greece: Results from the EMERGE multicenter retrospective chart review study. BMC Cancer. 2019 Jan 18;19(1):88.

Figure A: Overview of current drugs for breast cancer, demonstrating the pattern of novel therapeutic introductions and significant market uptake. These precedents demonstrate a strong market pull for Bria-IMT™.

- $2-5Bil Opportunity in Breast Cancer
- Up to $25Bil Opportunity across broad indications

***** Worldwide sales figure is based on SEC filings
** Approved for multiple cancer indications.

References for figure A:

1.https://pubmed.ncbi.nlm.nih.gov/31235441/
2.https://pubmed.ncbi.nlm.nih.gov/23810467/
3.https://pubmed.ncbi.nlm.nih.gov/25501126/
4.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8676999/
5.https://pubmed.ncbi.nlm.nih.gov/15699478/
6.https://pubmed.ncbi.nlm.nih.gov/18000498/
7.https://pubmed.ncbi.nlm.nih.gov/20124182/
8.https://www.nejm.org/doi/10.1056/NEJMoa1814213?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed
9.https://ascopubs.org/doi/10.1200/JCO.2023.41.16_suppl.1095
10.https://pubmed.ncbi.nlm.nih.gov/20421541/
11.https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5581697/
12.https://aacrjournals.org/clincancerres/article/26/20/5310/82934/A-Phase-II-Study-of-Abemaciclib-in-Patients-with
13.https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(12)70329-7/abstract
14.https://pubmed.ncbi.nlm.nih.gov/20421541/
15.https://pubmed.ncbi.nlm.nih.gov/21172893/

For further information on our lead candidate Bria-IMT™ clinical development, see “Bria-IMT™” in the “Production /Pipeline” section.

Competition

Currently available therapeutic options for breast cancer offer some hope for patients, but there is much room for improvement. Comparable studies looking primarily at second line or later treatment are shown in Table "A", below. Evaluating response rates (partial and complete responses = ORR), progression free survival ("PFS") and overall survival ("OS") from clinical trials in similar subjects with metastatic or recurrent breast cancer indicate that response rates range from 2.7% up to 59%, depending on the population studied and the intervention (median 24%). PFS ranges from 8 weeks to 12 months (median 5 months) and OS from 6 months to 31 months (median 13 months).

Table A: Studies evaluating second-line or later treatment options. Data depict an unpredictable response rate to treatment ranging from 6.9-59%, therefore establishing and confirming the opportunity for Bria-IMT™.

Study	Treatment & Design	# of Pts	ORR	PFS/TTP	OS
Licchetta[1]	Cyclophosphamide and megestrol acetate	29	31%	7.4 mo	13.4 mo
Harvey[2]	Docetaxel Monotherapy 60 mg/m2	122	22.1%	12.7 wk	10.6 mo
	Docetaxel Monotherapy 75 mg/m2	146	23.3%	15.0 wk	10.3 mo
	Docetaxel Monotherapy 100 mg/m2	139	36.0%	16.6 wk	12.3 mo
Rivera[3]	Docetaxel Monotherapy q3wk	59	35.6%	5.7 mo	18.3 mo
	Docetaxel Monotherapy qwk	59	20.3%	5.5 mo	18.6 mo
Gradishar[4]	ABI-007 (Nab paclitaxel)	229	33%	23.0 wk	65.0 wk
	Paclitaxel Monotherapy	225	19%	16.9 wk	55.7 wk
	ABI-007 (Nab paclitaxel) 2nd line	132	27%	20.9 wk	56.4 wk
	Paclitaxel Monotherapy 2nd line	136	13%	16.1 wk	46.7 wk
Perez[5]	Ixabepilone Monotherapy	126	11.5%	3.1 mo	8.6 mo
Leyland-Jones[6]	Trastuzumab with paclitaxel	32	59%	12.2 mo	
von Minckwitz[7]	Trastuzumab with capecitabine	78	48.1%	8.2 mo	25.5 mo
	Capecitabine Monotherapy	78	27.0%	5.6 mo	20.4 mo
Verma[8]	Trastuzumab emtansine	495	43.6%	9.6 mo	30.9 mo
	lapatinib plus capecitabine	496	30.8%	6.4 mo	25.1 mo
Geyer[9]	Lapatinib plus capecitabine	163	22%	8.4 mo	
	Capecitabine Monotherapy	161	14%	4.4 mo	
Bartsch[10]	Capecitabine and trastuzumab	40	20%	8 mo	24 mo
Blackwell[11]	Lapatinib Monotherapy	148	6.9%	8.1 wk	39.0 wk
	Lapatinib with trastuzumab	148	10.3%	12.0 wk	51.6 wk
Cortes[12]	Vinflunine	298			9.8 mo
	alkylating agent	296			7.2 mo
Kazmi[13]	Eribulin	229			9.1 mo
	Gemcitabine	134			9.1 mo
	Capecitabine	80			9.3 mo
O'Shaughnessy[14]	Sacituzumab	235	31%	4.6 mo	12.4 mo
	Treatment of Physicians Choice	233	4%	2.3 mo	6.7 mo
Tripathy[15]	Etirinotecan Pegol	92	4.8%	2.8 mo	7.8 mo
	Treatment of Physicians Choice	86	2.7%	1.9 mo	7.5 mo

MBC treated with second or higher lines of therapy has a very poor prognosis and few effective therapies that consistently induce long-term remission,[15] which indicates the market demand and clinical need for new and improved therapeutic drugs and treatment options in order to improve these response outcomes and patient survival rates. Thus, Bria-IMT™ has the potential to induce long-term remission, especially in combination with immunotherapies. Current treatment of MBC is outlined in Figure "B", below, which illustrates different therapeutic treatment options and drugs used upon diagnoses from biopsy and identification of breast cancer biomarkers.[16]

[1] Licchetta A, Correale P, Migali C, Remondo C, Francini E, Pascucci A, Magliocca A, Guarnieri A, Savelli V, Piccolomini A, Carli AF, Francini G. Oral metronomic chemo-hormonal-therapy of metastatic breast cancer with cyclophosphamide and megestrol acetate. J Chemother. 2010 Jun;22(3):201-4.

[2] Harvey, V. et al. Phase III Trial Comparing Three Doses of Docetaxel for Second-Line Treatment of Advanced Breast Cancer. J. Clin. Oncol. 24, 4963-4970 (2006).

[3] Rivera, E. et al. Phase 3 study comparing the use of docetaxel on an every-3-week versus weekly schedule in the treatment of metastatic breast cancer. Cancer 112, 1455-1461 (2008).

[4] Gradishar WJ. Taxanes for the treatment of metastatic breast cancer. Breast Cancer (Auckl). 2012;6:159-71.

[5] Perez, E. A. et al. Efficacy and Safety of Ixabepilone (BMS-247550) in a Phase II Study of Patients With Advanced Breast Cancer Resistant to an Anthracycline, a Taxane, and Capecitabine. J. Clin. Oncol. 25, 3407-3414 (2007).

[6] Leyland-Jones, B. et al. Pharmacokinetics, Safety, and Efficacy of Trastuzumab Administered Every Three Weeks in Combination With Paclitaxel. J. Clin. Oncol. 21, 3965-3971 (2003). Only 41% of patients had prior systemic chemotherapy.

[7] von Minckwitz G et el. Trastuzumab beyond progression: overall survival analysis of the GBG 26/BIG 3-05 phase III study in HER2-positive breast cancer. Eur J Cancer. 2011 Oct;47(15):2273-81. Prior therapy limited to trastuzamab alone or in combination with a taxane.

[8] Verma, S. et al. Trastuzumab Emtansine for HER2-Positive Advanced Breast Cancer. N. Engl. J. Med. 367, 1783-1791 (2012).

[9] Geyer, C. E. et al. Lapatinib plus Capecitabine for HER2-Positive Advanced Breast Cancer. N. Engl. J. Med. 355, 2733-2743 (2006).

[10] Bartsch, R. et al. Capecitabine and Trastuzumab in Heavily Pretreated Metastatic Breast Cancer. J. Clin. Oncol. 25, 3853-3858 (2007).

[11] Blackwell, K. L. et al. Randomized Study of Lapatinib Alone or in Combination With Trastuzumab in Women With ErbB2-Positive, Trastuzumab-

Refractory Metastatic Breast Cancer. J. Clin. Oncol. 28, 1124-1130 (2010).

[12] Cortes J, Perez-Garcia J, Levy C, Gómez Pardo P, Bourgeois H, Spazzapan S, Martínez-Jañez N, Chao TC, Espié M, Nabholtz JM, Gonzàlez Farré X, Beliakouski V, Román García J, Holgado E, Campone M. Open-label randomised phase III trial of vinflunine versus an alkylating agent in patients with heavily pretreated metastatic breast cancer. Ann Oncol. 2018 Apr 1;29(4):881-887. Doi: 10.1093/annonc/mdy051. PMID: 29481630.

[13] Kazmi S, Chatterjee D, Raju D, Hauser R, Kaufman PA. Overall survival analysis in patients with metastatic breast cancer and liver or lung metastases treated with eribulin, gemcitabine, or capecitabine. Breast Cancer Res Treat. 2020 Nov;184(2):559-565. Doi: 10.1007/s10549-020-05867-0. Epub 2020 Aug 17. Erratum in: Breast Cancer Res Treat. 2021 Jun;187(2):603. PMID: 32808239; PMCID: PMC7599186.

[14] O'Shaughnessy J, Brufsky A, Rugo HS, Tolaney SM, Punie K, Sardesai S, Hamilton E, Loirat D, Traina T, Leon-Ferre R, Hurvitz SA, Kalinsky K, Bardia A, Henry S, Mayer I, Zhu Y, Phan S, Cortés J. Analysis of patients without and with an initial triple-negative breast cancer diagnosis in the Phase 3 randomized ASCENT study of sacituzumab govitecan in metastatic triple-negative breast cancer. Breast Cancer Res Treat. 2022 Sep;195(2):127-139. Doi: 10.1007/s10549-022-06602-7. Epub 2022 May 11. PMID: 35545724; PMCID: PMC9374646.

[15] Tripathy D, Tolaney SM, Seidman AD, Anders CK, Ibrahim N, Rugo HS, Twelves C, Dieras V, Müller V, Tagliaferri M, Hannah AL, Cortés J. ATTAIN: Phase III study of etirinotecan pegol versus treatment of physician's choice in patients with metastatic breast cancer and brain metastases. Future Oncol. 2019 Jul;15(19):2211-2225. Doi: 10.2217/fon-2019-0180. Epub 2019 May 10. PMID: 31074641; PMCID: PMC7466911.

[16] NCCN Guidelines Version 2.2019, 07/02/2019 © 2019 National Comprehensive Cancer Network (NCCN®).

Figure B: Current treatment paradigm for metastatic breast cancer including between different treatment strategies and combination therapies dependent upon biomarker identification and activity within the breast cancer signaling pathway.

Of patients treated with trastuzumab for MBC, one study showed that 241/331 (72%) progressed within 27 months (32% per year) with median survival of 13-14 months (CI 10-15 months).[1] This indicates the high unmet need in this patient population which should facilitate regulatory review of novel therapies such as Bria-IMT™.

There are a number of cancer vaccines in development for breast cancer, including but not limited to TPIV200 (Marker Therapeutics, Inc.), AE-37 (Antigen Express), and Stimuvax (Merck KgA). While these development candidates are aimed at a number of different targets, and AE-37 has published data in the HER2 breast cancer patient population, there is no guarantee that any of these compounds will not in the future be indicated for treatment of low-to-intermediate HER2 breast cancer patients and become directly competitive with Bria-IMT.

While there are many biotech companies working to create an effective breast cancer vaccine, a significant gap remains in the effectiveness and safety of second or higher lines of therapy. The most studied targeted immunotherapy, Neuvax (Galena), a HER2 peptide vaccine, failed a Phase III trial, but there is encouraging data to support at least three ongoing clinical trials combining trastuzumab with HER2 epitope immunogens.[2] The National Cancer Institute ("NCI") randomized trial adding PANVAC (a poxviral-based immunogen) to docetaxel increased the median PFS from 3.9 months to 7.9 months and is to be used as a basis for larger, more sophisticated clinical trials.[3] An immunogen targeting a carbohydrate antigen, globo-H, was associated with improved PFS, but only in the subset able to mount antibody responses.[4] A Johns Hopkins breast cancer trial using a breast cancer cell line transfected with the gene for GM-CSF has not been positive but, using the same cell line with trastuzumab, 40% of patients enjoyed clinical benefit (CR+PR+stable) at one year.[5] Finally, the study of targeted cancer immunotherapies in combination with other therapies is receiving much attention, particularly combination with checkpoint inhibitors.[6]

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[1] Rossi, V.; Nole, F.; Redana, S.; Adamoli, L.; Martinello, R.; Aurilio, G.; Verri, E.; Sapino, A.; Viale, G.; Aglietta, M.; Montemurro, F., Clinical outcome in women with HER2-positive de novo or recurring stage IV breast cancer receiving trastuzumab-based therapy. Breast 2014, 23 (1), 44-9.

[2] Mittendorf, E. A.; Peoples, G. E., Injecting Hope-A Review of Breast Cancer Vaccines. Oncology (Williston Park) 2016, 30 (5), 475-81, 485.

[3] Heery, C. R.; Ibrahim, N. K.; Arlen, P. M.; Mohebtash, M.; Murray, J. L.; Koenig, K.; Madan, R. A.; McMahon, S.; Marte, J. L.; Steinberg, S. M.; Donahue, R. N.; Grenga, I.; Jochems, C.; Farsaci, B.; Folio, L. R.; Schlom, J.; Gulley, J. L., Docetaxel Alone or in Combination With a Therapeutic Cancer Vaccine (PANVAC) in Patients With Metastatic Breast Cancer: A Randomized Clinical Trial. JAMA Oncol 2015, 1 (8), 1087-95.

[4] Huang, C.; Yu, A.; Tseng, L., Randomized phase II/III trial of active immunotherapy with OPT-822/OPT-821 in patients with metastatic breast cancer. J Clin Oncol 2016, 34 (15).

[5] Chen, G.; Gupta, R.; Petrik, S.; Laiko, M.; Leatherman, J. M.; Asquith, J. M.; Daphtary, M. M.; Garrett-Mayer, E.; Davidson, N. E.; Hirt, K.; Berg, M.; Uram, J. N.; Dauses, T.; Fetting, J.; Duus, E. M.; Atay-Rosenthal, S.; Ye, X.; Wolff, A. C.; Stearns, V.; Jaffee, E. M.; Emens, L. A., A feasibility study of cyclophosphamide, trastuzumab, and an allogeneic GM-CSF-secreting breast tumor vaccine for HER2+ metastatic breast cancer. Cancer Immunol Res 2014, 2 (10), 949-61.

[6] McArthur, H. L.; Page, D. B., Immunotherapy for the treatment of breast cancer: checkpoint blockade, cancer vaccines, and future directions in combination immunotherapy. Clin Adv Hematol Oncol 2016, 14 (11), 922-933.

There are several other approaches to developing targeted breast cancer immunotherapies. These include using peptide cocktails, a triple peptide regimen, recombinant HER2, antigen-pulsed dendritic cells, DNA immunogens, whole cell allogeneic GM-CSF secreting SKBR3 or T47D cells, an (HLA)-A2/A3-restricted immunogenic peptide derived from the HER2 protein, oxidized mannan-MUC1, and personalized peptide immunogens.

Among the most promising results in patients with advanced disease have been using whole-cell preparations, particularly if the cells are engineered to express GM-CSF. We are taking this approach and capitalizing on positive initial results with Bria-IMT™ monotherapy in difficult to treat patients using a regimen that both limits regulatory T cell activity (using low dose cyclophosphamide pre-treatment) and boosts the immune response (using post-dose alpha interferon in the inoculation sites). The combination with PD-1 inhibitors is a logical extension of our findings where 21 of 23 MBC patients had demonstrable PD-L1 expression on the circulating tumor cells ("CTCs") and/or circulating cancer-associated macrophage-like cells ("CAMLs"). The overall strategy, once the initial milestones have been met, to enroll additional patients for product registration, will allow rapid progression of the best therapeutic option to a Biologics License Application ("BLA").

Cancer immunotherapy has become a significant growth area for the biopharmaceutical industry, attracting large pharmaceutical companies as well as small niche players. Generally, our principal competitors in the cancer immunotherapy market comprise both companies with currently approved products for various indications, such as manufacturers of approved bispecific antibodies, CAR-T cells, and checkpoint inhibitors, as well as companies currently engaged in cancer immunotherapy clinical development. The large and medium-size players who have successfully obtained approval for cancer immunotherapy products include Bristol-Myers Squib Company, Merck & Co., Inc., Genentech, Inc. (a subsidiary of Roche Holding AG), AstraZeneca PLC, Celgene Corporation, Johnson & Johnson/Janssen Pharmaceuticals, Amgen, Novartis, Acerta Pharmaceuticals (a subsidiary of AstraZeneca), Juno Therapeutics, Inc. (a subsidiary of Celgene), Kite Pharma, Inc., a wholly-owned subsidiary of Gilead Sciences, Inc. and Pfizer, Inc./EMD Serono, Inc. Most of these companies, either alone or together with their collaborative partners, have substantially greater financial resources than does BriaCell.

Companies developing novel products with similar indications to those we are pursuing are expected to influence our ability to penetrate and maintain market share. For patients with early stage breast cancer, adjuvant therapy is often given to prevent recurrence and increase the chance of long-term disease-free survival. Adjuvant therapy for breast cancer can include chemotherapy, hormonal therapy, radiation therapy, or combinations thereof. In addition, the HER2 targeted drug trastuzumab (HERCEPTIN), alone or in combination with pertuzumab (PERJETA), both manufactured and marketed by Roche/Genentech, may be given to patients with tumors with high expression of HER2 (IHC 3+), as well as other novel targets such as MUC1, which may be useful in treating breast cancer. In addition, the FDA approved the first ever immunotherapy regimen for breast cancer to the Roche/Genentech PD-L1 checkpoint inhibitor atezolizumab (TECENTRIQ), combined with Celgene's nab-paclitaxel (ABRAXANE) for TNBC that cannot be removed with surgery and is locally advanced or metastatic.

Many of our competitors, either alone or with their strategic partners, have substantially greater financial, technical and human resources than we do, and also have greater experience in obtaining FDA and other regulatory approvals of treatments and commercializing those treatments. Accordingly, our competitors may be more successful than us in obtaining approval for cancer immunotherapy products and achieving widespread market acceptance. Our competitors' treatments may be more effectively marketed and sold than any products we may commercialize, thus causing limited market share before we can recover the expenses of developing and commercializing of our cancer immunotherapy product candidate.

Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These activities may lead to consolidated efforts that allow for more rapid development of cancer immunotherapy product candidates.

These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, the ability to work with specific clinical contract organizations due to conflicts of interest, and the conduct of trials in the ability to recruit clinical trial sites and subjects for our clinical trials.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, price and the availability of reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are viewed as safer, more convenient or less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for our current product candidates or any other future product candidate, which could result in our competitors establishing a strong market position before we are able to enter the market.

Products/Pipeline

Bria-IMT™

About Bria-IMT ™

Bria-IMT™, BriaCell's lead candidate, is a whole-cell immunotherapy. Bria-IMT™ in combination with an immune check point inhibitor is undergoing pivotal Phase 3 clinical testing in patients with advanced MBC patients who have failed prior lines of therapy. The pivotal Phase 3 combination study is listed on ClinicalTrials.gov as NCT06072612.

Developed and characterized by a team of dedicated scientists and clinicians, Bria-IMT™ (SV-BR-1-GM) is a targeted immunotherapy being developed for the treatment of breast cancer. Bria-IMT™ is a genetically engineered human breast cancer cell line with features of immune cells and clinically applied as a targeted immunotherapy.

In short, Bria-IMT™ immunotherapy is a genetically engineered human breast cancer cell line derived from a grade II tumor which activates the immune system to attack and destroy breast cancer tumors.

Mechanism of Action of Bria-IMT™

The mechanism of action of Bria-IMT™ is currently under investigation. It is likely that the expression of certain breast cancer antigens (proteins expressed in breast cancer cells) in Bria-IMT™ generates strong T cell and potentially antibody responses - resulting in recognition and destruction of cancerous cells.[37]

Bria-IMT™ is designed to secrete GM-CSF, a factor that stimulates components of the immune system. Specifically, GM-CSF activates dendritic cells, the cells that start immune responses. These activated dendritic cells then activate T cells, a key component of the immune system, to recognize the tumor cells as foreign, and eliminate them. To amplify this action, we have combined Bria-IMT™ with other immune system activators including cyclophosphamide (used in low doses to reduce immune suppression), and interferon-α, a cytokine that further activates the immune system. We believe this approach of simultaneous activation of the immune system via different pathways will improve the immune system response to attack and destroy cancer cells.

Pivotal Phase 3 Clinical Study of Bria-IMT™ in Combination with an Immune Check Point Inhibitor in Metastatic Breast Cancer

Bria-IMT™ is currently under Fast Track Designation by the FDA intended to accelerate the review process of novel treatments that address unmet medical needs. Positive completion of the pivotal study, following review by the FDA, could lead to full approval of the Bria-IMT™ immune checkpoint inhibitor combination in advanced metastatic breast cancer.

The FDA has agreed that improvement in overall survival in the Bria-IMT™ combination arm as compared to the physician's choice of treatment arm will be the primary endpoint of the study. The study is expected to enroll 177 patients in the Bria-IMT™ combination therapy arm and 177 patients in the treatment of physician's choice arm. To gather additional information on the Bria-IMT™ regimen alone, 50 patients are expected to be enrolled in this regimen and will be eligible for combination therapy following their initial post treatment evaluation. The study will have an interim evaluation for efficacy which could result in early completion of the study. We expect frequent and responsive FDA communication under our Fast Track status during our pivotal Phase 3 study.

The successful completion of the pivotal study would allow BriaCell to subsequently submit a Biologics License Application and accelerate the path to commercialization.

BriaCell's partnership with New York Cancer & Blood Specialists ("NYCBS") as clinical site with more than 30 locations and 35 hospital affiliations throughout Nassau and Suffolk counties, in the Bronx, Manhattan, Queens, Staten Island, and Brooklyn to conduct its pivotal Phase 3 Study of Bria-IMT™ in Advanced Breast Cancer. Currently the Phase 3 study has 14 locations throughout the USA as noted in the ClinicalTrials.gov listing https://clinicaltrials.gov/study/NCT06072612.

In collaboration with Prevail InfoWorks, Inc. ("InfoWorks"), a Philadelphia, PA based contract research organization, BriaCell continues to recruit additional sites to speed up the patient recruitment process. BriaCell has signed a Master Service and Technology Agreement ("MSTA") agreement with InfoWorks to provide clinical services and technologies for BriaCell's upcoming pivotal study in advanced metastatic breast cancer. Services include clinical site coordination, project management, clinical monitoring and pharmacovigilance (safety management) services, and the use of InfoWork's integrated real-time data analytics platform, The Single Interface ®, for clinical support and real-time data analysis.

In May 2023, Prevail Partners, LLC ("Prevail Partners"), an investment fund and affiliate of InfoWorks, purchased 463,408 BriaCell common shares at a price of $8.63 for gross proceeds of $4 million, representing a 20% premium to the trailing thirty (30) trading day volume-weighted average price of the common shares of the Company on the Nasdaq Stock Exchange.

Phase 1/2 Clinical Trial of Bria-IMT™ in Combination with Immune Check Point Inhibitors in Advanced Metastatic Breast Cancer

BriaCell has been conducting a Phase 1/2a clinical trial of Bria-IMT™, in combination with immune checkpoint inhibitors such as pembrolizumab (KEYTRUDA®; manufactured by Merck & Co., Inc.) and retifanlimab, an immune checkpoint inhibitor manufactured by Incyte. The combination study is listed in ClinicalTrials.gov as NCT03328026 under FDA-approved BB-IND 10312 under protocol BRI-ROL-001 at ten clinical sites throughout the United States.

BriaCell announced benchmark-beating patient survival and clinical benefit in advanced metastatic breast cancer with median overall survival of 13.5 months in BriaCell's advanced metastatic breast cancer patients vs. 6.7-9.8 months[1] for similar patients reported in the literature.

The ongoing study of BRI-ROL-001 combination therapy studies of the Bria-IMT™ regimen with immune checkpoint inhibitors (CPI). In the ongoing study of BRI-ROL-001, in phase I the Bria-IMT™ regimen was dosed in combination with Keytruda ® in 11 patients and in 12 patients with retifanlimab, with one patient starting on the combination with Keytruda® and crossing-over to the combination with retifanlimab (22 patients total). In phase II of the study, the Bria-IMT™ regimen is being dosed in combination with retifanlimab with patients randomized to either receive the Bria-IMT™ regimen first (16 patients) or retifanlimab first (16 patients). For the 11 patients treated in combination with Keytruda® in phase I, the disease control data is shown below:

- 11 patients were treated with Bria-IMT™ + Keytruda®
- All patients were very heavily pre-treated with a median of 7 prior systemic therapy regimens (i.e. chemotherapy), further underscoring BriaCell's positive patient outcomes
- Tolerability excellent with no dose-limiting toxicities
- Clinical benefit demonstrated: 1 PR and 3 SD in 8 immune responders

For the 12 patients treated in combination with retifanlimab in phase I, the disease control data is shown below:

- 12 patients were treated with Bria-IMT™ plus retifanlimab
- All patients were very heavily pre-treated with a median of 5 prior systemic therapy regimens (i.e. chemotherapy), further underscoring BriaCell's positive patient outcomes
- Tolerability excellent with no dose-limiting toxicities
- Efficacy: 70% (7/10) of evaluable patients showed disease control (5/10 evaluable patients including 1 PR and 4 SD) and/or progression-free survival (PFS) benefits compared with their last therapy regimen.

The overall survival of the patients for all patients on this study has been evaluated in an ongoing fashion. Since the study was largely on hold during COVID (2020 and 2021), patients dosed in 2019 and 2020 have been followed for a longer time. Therefore survival data has been evaluated for patients dosed before 2022 and since 2022. This should be considered in the context of clinical studies in patients with advanced breast cancer who have failed at least 2 prior regimens. Several recent publications are noted here:

- Cortes J, et al. Annals of Oncology 2018: Open-label randomized Phase 3 trial
- Patients: Median 4 prior lines of Rx; ~20% HER2 positive, ~20%TNBC; n= 298 vs 296 (vinflunine vs alkylating agent)
- ***Overall Response Rate (ORR) 6% vs 4%; Clinical Benefit Rate (CBR) 44% vs 35%; Progression Free Survival (PFS) 1.9 vs 2.5 months; Overall Survival (OS) 9.3. vs 9.1 months***
- Kazmi S, et al. Breast Cancer Res Treat. 2020 Aug 17: Overall survival analysis
- Patients: 2 prior lines of Rx; 229 Rx w eribulin, 134 gemcitabine, 80 capecitabine; 29% TNBC, 62% HR+/HER2-, 9% HER2+
- **Median OS eribulin 9.8 months, gemcitabine 7.2 months, capecitabine 9.1 months**
- O'Shaughnessy J et al. Breast Cancer Res Treat. 2022: Phase 3 randomized ASCENT study
- Patients: 4-5 prior lines of Rx; 235 on Sacituzumab, 233 on TPC; 31% non-TNBC initially, 69% TNBC at Dx
- **Patient w/o initial TNBC: ORR 31% vs 4%; CBR 44% vs 7%; PFS 4.6 vs 2.3 months; OS 12.4 vs 6.7 months**
- Patients w initial TNBC: ORR 36% vs 5%; CBR 45% vs 10%; PFS 5.7 vs 1.6 months; OS 12.1 vs 6.9 months
- Tripathy D, et al. JAMA Oncol. 2022: Phase 3 ATTAIN Randomized Clinical Trial
- Patients:~90% ≥4 prior lines of Rx; 92 on Etirinotecan Pegol 86 TPC; ~15% HER2+ ~40% TNBC
- **ORR 4.8% vs 2.7%; CBR 24.1% vs 9.5%; PFS 2.8 vs 1.9 months; OS 7.8 vs 7.5 months**

In contrast, the Bria-IMT™ regimen, using the Phase 3 formulation, with a CPI has shown a median overall survival (OS) of 13.4 months for all patients by the Kaplan Meier method, as shown in the Figure below. For patients treated since 2022, the median OS was estimated at 15.6 months.

[1]Cortes J, et al. Annals of Oncology 2018; Kazmi S, et al. Breast Cancer Res Treat. 2020 Aug 17; O'Shaughnessy J et al. Breast Cancer Res Treat. 2022; Tripathy D, et al. JAMA Oncol. 2022

Figure B. Overall Survival of Patients with Metastatic Breast Cancer treated with the Bria-IMT™ regimen using the Phase 3 formulation with a CPI.

Letter of Intent from Weill Cornell Medicine Outlining Plans to Initiate a Phase 2 Clinical Trial of Bria-IMT™ in High-Risk Early-Stage Triple Negative Breast Cancer

In August, 2023, BriaCell announced that it has accepted a letter of intent from Dr. Massimo Cristofanilli, Director of Breast Medical Oncology and Associate Director of Precision Medicine in the Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine, outlining the parties' plans and commitment, upon regulatory approval, to initiate a Phase 2 investigator-initiated clinical study to evaluate BriaCell's novel immunotherapy, Bria-IMT™, in combination with a check point inhibitor, in early stage, newly diagnosed, high-risk triple negative breast cancer patients who have failed to achieve a pathological complete response in the neoadjuvant setting. As of the date of this filing, the investigative study has not yet commenced, as the Company is focusing on its pivotal Phase 3 study.

Manufacturing

We do not own or operate manufacturing facilities for the production of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredients, and finished product candidate for our clinical trials. We currently employ internal resources and third-party consultants to manage our manufacturing contractors.

Bria-IMT™ is currently manufactured under current Good Manufacturing Practices ("cGMP") pursuant to agreements with UC Davis and with Fuji, which is located in Thousand Oaks, California.

On June 11, 2015, the Company entered into an Agreement for Services with The Regents of the University of California, acting for and on behalf of UC Davis, pursuant to which UC Davis manufactures Bria-IMT™ (previously known as BriaVax) at its GMP facility. The Company pays UC Davis certain hourly rates depending on the specific services provided by UC Davis in connection with its manufacturing of Bria-IMT™.

On July 5, 2022, BriaCell announced that it had entered into a manufacturing service agreement with Waisman Biomanufacturing at the University of Wisconsin-Madison ("Waisman"), to manufacture Bria-Pros™, BriaCell's off-the-shelf personalized immunotherapy for prostate cancer, for anticipated use in clinical studies. Waisman is a leading contract manufacturing organization with experience in the manufacturing of cellular therapies for clinical trials. Under the terms of the agreement, Waisman will be responsible for GMP manufacturing of Bria-Pros™ for anticipated use in clinical studies. Waisman's expert team will be working closely with BriaCell's scientific and product development teams to ensure timely production of Bria-Pros™ in compliance with applicable regulatory requirements by the FDA.

Pursuant to the Company's master services agreement with Fuji, dated May 29, 2023, to manufacture Bria-IMT™, for anticipated use in clinical studies including the Phase 3 study. Fuji is a leading contract manufacturing organization with experience in the manufacturing of cellular therapies for clinical trials. Under the terms of the agreement, Fuji will be responsible for GMP manufacturing of Bria-IMT™ for anticipated use in clinical studies. Fuji's expert team will be working closely with BriaCell's scientific and product development teams to ensure timely production of Bria-IMT™ in compliance with applicable regulatory requirements by the FDA.

Bria-OTS™

- **Bria-OTS™: Personalized Off-the-Shelf Immunotherapy**

BriaCell Phase 1/2 Study of Bria-OTS™, also known as Bria-BRES™, in metastatic breast cancer is open. The Phase 1/2 clinical study is listed on ClinicalTrials.gov as NCT06471673.

- Bucket trial with additional cancer indications planned
- Enhanced version (Bria-OTS+™) scheduled to enter the clinic 1H2025 starting with Bria-Pros™ (prostate cancer)
- We believe Bria-IMT™ is most effective in human leukocyte antigens (HLA) – type matched patients
- Bria-OTS™ is engineered to express 15 unique HLA types through 4 independent cell lines
- Provides matched treatment to greater than 99% of patients
- Simple saliva test provides HLA matched personalized off-the-shelf Bria-OTS™ immunotherapy
- HLA matched off-the-shelf therapy is faster and less costly than other expensive and complex personalized immunotherapies
- BriaCell received a Small Business Innovation Research (SBIR) grant from the National Cancer Institute (NCI) to further develop Bria-OTS™
- Ongoing collaboration with the NCI to investigate the Bria-OTS™ mechanism action
- BriaCell has secured numerous US and international patents for Bria-OTS™
- Similar immunotherapies are in development for prostate cancer (Bria-Pros™), lung cancer (Bria-Lung™), and melanoma (Bria-Mel™)

Development of Additional Immunotherapy Cell Lines

- Based on these observations, BriaCell is extending this technology to other types of cancer by developing additional immunotherapy cell lines.

- Cell lines currently being genetically engineered include a breast cancer cell line, a prostate cancer cell line, a non-small cell lung cancer cell line and a melanoma cell line.

- The genetic engineering has been completed for the breast cancer cell line and GMP manufacturing completed. BriaCell is currently evaluating its personalized immunotherapy, Bria-BRES™, as monotherapy and in combination with PD-1 inhibitor tislelizumab, in a phase 1/2a study in metastatic breast cancer (ClinicalTrials.gov **NCT06471673**). The Phase 1/2 study is a bucket trial with initial study in breast cancer with extensions to prostate cancer, lung cancer and melanoma. .

  On May 28, 2024, BriaCell announced a clinical supply agreement with BeiGene for Bria-OTS™ First in Human Study. Study is to evaluate the effects of Bria-OTS™ in combination with anti-PD-1 antibody tislelizumab, in advanced, late stage, heavily pretreated metastatic breast cancer.

  In September 2024, BriaCell announced positive pre-IND meeting with FDA for Bria-PROS+™ for prostate cancer

- Enhanced version (Bria-OTS+™) is scheduled to enter the clinic 1H2025 starting with Bria-Pros™ (prostate cancer)

  BriaCell is currently developing the proprietary Bria-OTS+™ platform as the company pursues the development of Bria-BRES+™, Bria-LUNG+™ and Bria-MEL+™, for breast cancer, lung cancer and melanoma, respectively.

- IND filings for these immunotherapy cell lines are anticipated starting in 2025.

Early Phase Programs

On August 4, 2022, BriaCell announced that it has secured an exclusive license from University of Maryland, Baltimore County ("UMBC") to develop and commercialize Soluble CD80 ("sCD80") as a biologic agent for the treatment of cancer. Under the terms of the agreement, BriaCell has the worldwide rights to develop and commercialize sCD80, while UMBC maintains ownership of the patents. BriaCell will pay royalties to UMBC upon the commercialization of the product plus patent management costs. The licensing agreement was coordinated by UMBC's Office of Technology Development.

The patents are listed as the following: USPN 8,956,619 B2; USPN 9,650,429 B2; USPN 10,377,810 B2

CD80 is an important co-stimulatory molecule present on antigen-presenting cells and key for activating T cells. CD80 also acts as an immune checkpoint inhibitor. As noted in the patents, significant data has been generated showing that in animal models sCD80 is capable of enhancing anti-cancer immune responses and shrinking tumors in model systems. The sCD80 appears to act both as an immune stimulator and checkpoint inhibitor. This makes it an ideal candidate to combine with BriaCells's cellular immunotherapy platform.

sCD80 project is temporarily on hold as the Company focused on its pivotal Phase 3 study.

Marketing and Sales Strategy

The product will initially be marketed to oncologists who are well-versed in the use of immunotherapy for cancer. Partnering with other pharmaceutical companies in order to market combinations with a number of drugs is also an option that we intend to pursue. This study will utilize a frozen formulation which consists of irradiated SV-BR-1-GM cells in viable freezing media. This formulation will permit stockpiling of immunotherapy so that it can be sent on demand to clinical sites. The eventual goal is to reach all oncologists who treat late-stage breast cancer, either by direct outreach or by partnering with another company that has an established presence in the oncology space.

Our future commercial strategy may include the use of strategic partners, distributors, a contract sale force, or the establishment of our own commercial and specialty sales force, as well as similar strategies for regions and territories outside the United States. We plan to further evaluate these alternatives as we approach approval for the use of our product candidates for one or more indications.

Other Commercial Considerations

There is a high unmet medical need in late-stage breast cancer, providing potential for accelerated approval of Bria-IMT™. The FDA is interested in facilitating the availability of novel therapies of patients with unmet medical needs, especially those that can target the population most likely to respond. In addition, the FDA has granted "Fast Track" status to BriaCell's lead candidate, Bria-IMT™, for the treatment of metastatic breast cancer. These two facts may help facilitate the accelerated approval of Bria-IMT™.

Production and Marketing Plan

Bria-IMT™ cells grow in simple tissue culture media and are irradiated prior to inoculation. Bria-IMT™ manufacturing will be performed by Contract Manufacturing Organizations. We have been working with FUJIFILM Diosynth Biotechnologies ("Fuji") and the University of California, Davis Health System ("UC Davis") GMP facility, who have developed a frozen formulation where the cells are grown, harvested and irradiated, followed by cryopreservation in a viable state. The cells are stockpiled and shipped directly to clinical sites for inoculation. Each lot of Bria-IMT™ is tested for potency (i.e. GM-CSF production), identity (i.e. HER2+ and ER/PR-) and adventitious agents to rule out contamination with infectious agents. To date, there have been no issues with these tests. Additional manufacturing facilities have been evaluated and may be enlisted as demand grows.

Marketing will target oncologists who are well-versed in the use of immunotherapy and especially breast cancer treatment centers. The initial target will be patients with metastatic or recurrent breast cancer who have failed at least two prior treatment regimens. We plan to develop the clinical data for Bria-IMT™ and to use this information to reach out to oncologists seeking additional therapeutic options for their patients. We will include in this effort a physician education campaign targeting the oncologists most likely to treat metastatic breast cancer. As these physicians become more aware of the data regarding Bria-IMT™ in breast cancer, we will make sure they also understand how best to use Bria-IMT™ in combination with other therapies that have complementary synergistic mechanisms of action. This will also come from the clinical studies described above focusing on combination therapy. Partnering with other pharmaceutical companies in order to market a number of drugs is also an option that we intend to pursue. Our eventual goal is to reach all oncologists who treat late stage breast cancer, either by direct outreach or by partnering with another company that has an established presence in the oncology space.

License Agreements

On August 4, 2022, BriaCell announced that it has secured an exclusive license from University of Maryland, Baltimore County (UMBC) to develop and commercialize Soluble CD80 (sCD80) as a biologic agent for the treatment of cancer. Under the terms of the agreement, BriaCell has the worldwide rights to develop and commercialize sCD80, while UMBC maintains ownership of the patents. BriaCell will pay royalties to UMBC upon the commercialization of the product plus patent management costs. The licensing agreement was coordinated by UMBC's Office of Technology Development.

On July 24, 2017, the Company entered into a Share Exchange Agreement with its wholly-owned subsidiary, BriaCell Therapeutics Corp., Sapientia, and all the shareholders of Sapientia. Sapientia, a biotechnology company based in Havertown, PA, is developing novel targeted therapeutics for multiple indications, including several cancers and fibrotic diseases.

Pursuant to the terms of the Share Exchange Agreement, BriaCell Therapeutics Corp. agreed to acquire from the Sapientia shareholders all of the issued and outstanding shares in the capital of Sapientia in consideration to the Sapientia shareholders, pro rata, of an aggregate of 8,333 common shares in the capital of BriaCell (the "Transaction"), which were issued on September 5, 2017.

As part of the Transaction, BriaCell acquired the license agreement Sapientia entered into with Faller-Williams Technology ("FWT"), dated March 16, 2017 (the "License Agreement"), pursuant to which BriaCell acquired all rights, including composition of matter patents (the "PKCδ Patents"), and preclinical study data to a novel therapeutic technology platform, PKCδ inhibitors, which represents a unique, highly-targeted approach to treat cancer and to boost the immune system.

Pursuant to the License Agreement, FWT is eligible to receive certain milestone payments, including i) $5,000,000 upon the filing of each New Drug Application with the FDA with respect to products disclosed and/or described in the PKCδ Patents (the "PKCδ Products"); ii) $25,000,000 upon final approval of each New Drug Application by the FDA for the marketing of a PKCδ Product; iii) $1,000,000 upon the filing of each Marketing Authorization Application ("MAA") with the Medicines and Healthcare Products Regulatory Agency of United Kingdom or the Committee for Medicinal Products for Human Use of the European Commission with respect to a PKCδ Product; and iv) $5,000,000 upon the final approval of each MAA with the Medicines and Healthcare Products Regulatory Agency of United Kingdom or the Committee for Medicinal Products for Human Use of the European Commission for the marketing of a PKCδ Product.

FWT is eligible to receive certain royalty payments under the License Agreement. Following the first commercial sale of a PKCδ Product in the United States, FWT shall receive i) 5% of worldwide net sales of PKCδ Products encompassed by one or more valid claims of the PKCδ Patents and/or improvements thereto, and ii) 2.5% of worldwide net sales from PKCδ Products not encompassed within one or more valid claims of the PKCδ Patents. Additionally, upon BriaCell's receipt of marketing approval for a PKCδ Product from the FDA, the Medicines and Healthcare Products Regulatory Agency of United Kingdom, the Committee for Medicinal Products for Human Use of the European Commission or an equivalent authority, FWT shall receive minimum royalty payments of $250,000 per year.

Unless terminated earlier pursuant to the provisions therein, the License Agreement shall expire ten years after the last PKCδ Patent expires.

Intellectual Property

The proprietary nature of, and protection for, the Company's current and/or any future product candidates, processes and know-how are important to its business, as is its ability to operate without infringing on the proprietary rights of others, and to prevent others from infringing its proprietary rights. The Company seeks patent protection in the U.S. and internationally for its current and future product candidates it may develop through other technology. In order to protect its proprietary technologies, the Company relies on combinations of applications for patent and trade secret protection, as well as confidentiality agreements with employees, consultants, and third parties.

The Company has filed and owns or have licensed all rights in the following pending patent applications and issued patents:

Filed with the United States Patent and Trademark Office ("USPTO") on June 14, 2004, U.S. Patent No. 7,674,456 B2, includes claims to the following:

1. Compositions comprising SV-BR-1 and SV-BR-1-GM cells

2. Therapeutic methods of using said compositions

On February 27, 2017, BriaCell™ filed an international patent application under the Patent Cooperation Treaty (PCT) to further expand its intellectual property portfolio underlying the Company's current and anticipated pipeline of whole-cell cancer immunotherapeutics including Bria-IMT™ and Bria-OTS™. The PCT application (PCT/US2017/019757) claims priority to two provisional patent applications filed by the Company with the USPTO in 2016. It, in essence, provides the framework for additional whole-cell cancer immunotherapeutics beyond Bria-IMT™ and strategies for patient-specific selection of the most likely effective whole-cell immunotherapeutic (BriaDx™). The PCT application entered the National Phase in the second half of 2018 and was granted in Japan on June 21, 2021.

BriaCell was awarded an Australian patent (Patent No. 2017224232, extends to February 27, 2037) covering composition of matter and method of use for its whole-cell cancer immunotherapy technology in Australia.).

BriaCell has also received an Issue Notification from the USPTO for the composition of matter and method of use of its personalized off-the-shelf cell-based immunotherapy for cancer. The patent was issued on January 24, 2023 as US Patent No. 11,559,574 B2 with the term extending to May 25, 2040.

On July 24, 2017, BriaCell obtained the exclusive license to certain patents related to PKCδ inhibitor technology, including patents to specific compounds, methods of using the compounds, and methods of assessing patients regarding the compounds. These patents include U.S. Patent No. 9,364,460, which was issued on June 14, 2016; U.S. Patent No. 9,572,793, which issued on February 21, 2017; U.S. Patent No. 9,844,534, which was issued December 19, 2017; and EP Patent No. 2897610, which was issued on January 10, 2018.

To the knowledge of the Company's management, there are no contested proceedings or third-party claims over any of our patent applications. Our success depends upon our ability to protect our technologies through intellectual property agreements including patents, trademarks, know-how, and confidentiality agreements. However, there can be no assurance that the above-mentioned patent applications will be approved by the appropriate agencies.

All of the technology for which patents are currently sought is owned by the Company. Our patents are entirely owned or exclusively licensed by the Company.

Employees

As of the date of this filing, we had seventeen full-time employees and one part-time employee, located in various US states including: NY, FL, PA, SC, NV and NJ. We also have international employees located in Canada and Israel.

For the year ended July 31, 2024, the average number of employees was seventeen, of whom four were executive management.

Research and Development Activities and Costs

For information regarding our clinical studies, please see above under the caption "*Description of the Business - Clinical Trials.*"

For the years ended July 31, 2024 and 2023, we incurred $26,442,821 and $14,264,048, respectively, of net research and development expenses (excluding share based compensation allocated to research and development employees)

Property, Plant and Equipment

The Company does not own any real property. BriaCell's corporate offices in Canada are located at Suite 300, Bellevue Centre, 235-15th Street, West Vancouver, BC V7T 2XI, and its corporate and research offices in the United States are located at 2929 Arch Street 3rd Floor, Philadelphia, PA 19104.

We consider our current office and laboratory space sufficient to meet our anticipated needs for the foreseeable future and suitable for the conduct of our business.

During the year ended July 31, 2024, we purchased certain laboratory equipment in the gross amount of $456,801.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. Along with third-party contractors, we will be required to navigate the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our current or future product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies[1] performed in accordance with the FDA's current Good Laboratory Practices ("GLP") regulations;
- submission to the FDA of an Investigational New Drug Application ("IND"), which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board ("IRB") or ethics committee at each clinical site before the trial is begun;
- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application ("BLA"), after completion of all pivotal clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP, and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with current Good Clinical Practices ("GCP"); and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually when significant changes are made.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our current or future product candidates will be granted on a timely basis, if at all. Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and *in vitro* studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

[1] Note that the FDA has waived the requirement for animal studies as Bria-IMT™, Bria-BRES™ and Bria-PROS+™ are human cellular vaccines and data from animal studies would be uninterpretable.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the clinical trial until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by a Data & Safety Monitoring Board ("DSMB") organized by the clinical trial sponsor, which provides authorization for whether or not a clinical trial may move forward at designated check points based on access to certain data from the clinical trial, and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects, or based on other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical trial results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- **Phase 1**-The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- **Phase 2**-The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials. In some cases, the FDA will grant preliminary marketing authorization for drugs treating areas of high unmet medical need based on Phase 2 clinical trials. If granted, they will also require confirmatory Phase 3 evaluation post-marketing. BriaCell is evaluating Bria-IMT in patients with breast cancer who have failed at least two prior lines of therapy. In this population there is no approved therapy. Therefore, the development plan for Bria-IMT is an area of high unmet medical need. It is anticipated that BriaCell will not need to complete Phase 3 clinical trials prior to submitting the marketing application for Bria-IMT in patients with advanced breast cancer who have failed at least two prior lines of therapy. In this case, a confirmatory Phase 3 evaluation post-marketing will be required. It is anticipated that this would consist of a randomized, controlled clinical trial of Bria-IMT in combination with immune checkpoint inhibitors compared with best available therapy. However, this design is subject to negotiation with the FDA.

- **Phase 3**-The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

- **Phase 4**-In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of the BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial user fee to FDA, and the sponsor of an approved BLA is also subject to annual product and establishment user fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within ten months after it accepts the application for filing, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA accepts the application for filing. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and whether the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a product candidate with Fast Track designation, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A Fast Track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA accepts the application for filing. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA accepts the application for filing. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the Accelerated Approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict clinical benefit, or a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit.

In addition, a sponsor may seek FDA designation of its product candidate as a Breakthrough Therapy, if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis.

Fast Track, Priority Review and Breakthrough Therapy designations do not change the standards for approval but may expedite the development or approval process.

Other Healthcare Laws and Compliance Requirements

Our sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services, and state and local governments. Our promotional and scientific/educational programs must comply with the federal Anti-Kickback Statute, the Foreign Corrupt Practices Act, the False Claims Act ("FCA"), the Veterans Health Care Act, physician payment transparency laws, privacy laws, security laws, and additional state laws similar to the foregoing.

The federal Anti-Kickback Statute prohibits, among other things, the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare, Medicaid or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham research or consulting and other financial arrangements with physicians. Further, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. Many states have similar laws that apply to their state health care programs as well as private payors.

The FCA imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. Actions under the FCA may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the FCA can result in significant monetary penalties and treble damages. For example, the federal government is using the FCA, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multibillion dollar settlements under the FCA in addition to individual criminal convictions under applicable criminal statutes. In addition, companies have been forced to implement extensive corrective action plans, and have often become subject to consent decrees or corporate integrity agreements, restricting the manner in which they conduct their business. The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") also created federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "Affordable Care Act"), among other things, imposed new reporting requirements on drug manufacturers for payments or other transfers of value made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties**.** Certain states also mandate implementation of commercial compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians and other healthcare professionals.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act ("HITECH") and their respective implementing regulations, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increases the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gives state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to it, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. We cannot assure you that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Although we currently believe that third-party payors will provide coverage and reimbursement for our product candidates, if approved, these third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our product candidates. Seeking coverage and reimbursement from third-party payors can be time consuming and expensive. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis.

Foreign Regulation

In addition to regulations in the United States, we are and will be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have processes that require the submission of a clinical trial application much like an IND prior to the commencement of human clinical trials. In Europe, for example, a clinical trial application ("CTA") must be submitted to the competent national health authority and to independent ethics committees in each country in which a company plans to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the European Union (the "E.U.") member states resulting from the national implementation of underlying E.U. legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of a new drug or medicinal product in the E.U., a sponsor must obtain approval of a marketing authorization application. The way in which a medicinal product can be approved in the E.U. depends on the nature of the medicinal product.

The centralized procedure results in a single marketing authorization granted by the European Commission that is valid across the E.U., as well as in Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated as "orphan drugs" and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients or animal health at the European Community level.

Under the centralized procedure in the E.U., the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the Committee for Medicinal Products for Human Use ("CHMP")), with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: (i) the seriousness of the disease to be treated, (ii) the absence of an appropriate alternative therapeutic approach, and (iii) anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The Mutual Recognition Procedure ("MRP") for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the E.U. The MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products, and is based on the principle of recognition of an already existing national marketing authorization by one or more member states.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a member state of the E.U. that is used as reference in order to obtain marketing authorizations in other E.U. member states. In the MRP, a marketing authorization for a drug already exists in one or more member states of the E.U. and subsequently marketing authorization applications are made in other E.U. member states by referring to the initial marketing authorization. The member state in which the marketing authorization was first granted will then act as the reference member state. The member states where the marketing authorization is subsequently applied for act as concerned member states.

The MRP is based on the principle of the mutual recognition by E.U. member states of their respective national marketing authorizations. Based on a marketing authorization in the reference member state, the applicant may apply for marketing authorizations in other member states. In such case, the reference member state shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all member states, together with the approved summary of product characteristics, labeling and package leaflet. The concerned member states then have 90 days to recognize the decision of the reference member state and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any E.U. member state refuse to recognize the marketing authorization by the reference member state, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, member states shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products or Veterinary Medicinal Products, as appropriate.

For other countries outside of the E.U., such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Plan of Arrangement

On August 31, 2023, the Company closed a plan of arrangement spinout transaction (the "Arrangement"). Pursuant to the Arrangement, certain pipeline assets of the Company were spun-out to BriaPro Therapeutics Corp. ("BriaPro" or "SpinCo"), including Bria-TILsRx™ and protein kinase C delta (PKCδ) inhibitors for multiple indications including cancer (the "BriaPro Assets"), resulting in a two-third (2/3) owned subsidiary of the Company with the remaining one-third (1/3) held by the Company's shareholders. BriaPro has acquired the entire right and interest in and to the BriaPro Assets in consideration for the issuance by BriaPro to the Company of BriaPro's common shares. Under the terms of the Arrangement, for each common share of the Company held immediately prior to closing, the shareholders of the Company received one common share of BriaPro, and one new common share of the Company (retiring their old share) having the same terms and characteristics as the existing common shares of the Company. The Company's common shares and public warrants remained listed on the Nasdaq Capital Market and the common shares remained listed on the Toronto Stock Exchange, and SpinCo is an unlisted reporting issuer in Canada. As part of the Arrangement, the Company obtained a third-party independent valuation for BriaPro which amounted to $1.75 million. Based on the number of issued shares of BriaPro, this amounts to $0.0365 per BriaPro share.

BriaPro is a pre-clinical stage immunotherapy company developing binding agents and proteins with the intention to boost the ability of the body's own cancer-fighting cells to destroy cancerous tumors. Using artificial intelligence ("AI") with ImmunoPrecise Antibodies and Receptor AI, BriaPro will identify drug candidates.

The lead drug discovery candidates for BriaPro includes:

- Bria-TILsRx™: Multi-Specific Binding Reagents - Immunotherapy for Cancer: being developed in collaboration with ImmunoPrecise Antibodies.
- Small Molecule Program: Protein Kinase C delta (PKCδ) Inhibitors being developed with Receptor AI.

The power of AI in drug candidate selection has been hailed by experts and investments in AI-driven drug discovery companies have tripled over the past four years, reaching $24.6 billion in 2022.[2] Using AI technology to identify the next blockbuster therapies can help eliminate some of the guesswork that typically requires hundreds of lab experiments-often spread over many years-to identify promising molecules.

Instead of coming up with tens of thousands of compounds to figure out, computers suggest testing ten compounds in a lab, then getting feedback from the lab results. The machines learn from those results to make a better prediction to provide the next hundred candidates for testing and ultimately filter to one molecule.

Over the course of the next year, BriaPro expects to screen several different multi specific binding reagents for activity in vitro as well as in mouse models of cancer. BriaPro also expects to select at least one candidate to advance into IND enabling studies. Human clinical studies are expected to be initiated in the first half of 2025. In parallel, BriaPro will continue to optimize the structure of its proprietary protein kinase C delta inhibitors and advance to the candidates election stage. Human clinical studies are expected to be initiated in the second half of 2025.

Recent Developments

On January 4, 2024, BriaCell disclosed images confirming robust anti-tumor activity in patient with "Eye-Bulging" metastatic breast cancer. Significant reduction of metastatic breast cancer tumor behind-the-eye was reported after only 3 cycles. Powerful anti-tumor response associated with reduction in proptosis (eye-bulging) and reduced ocular pain. Heavily pre-treated patient had failed 7 prior regimens including antibody-drug conjugate therapy and remains on BriaCell treatment. MRI images showed the tumor in the right orbit behind the eye with the eye not being visible pre-treatment. After treatment with the Bria-IMT™ regimen, the eye becomes visible as it has regained its normal position. Reduction in tumor size was also seen. Images of this patient are shown further below.

On February 6, 2024, BriaCell announced initiation of Good Manufacturing Practice (GMP) of its lead candidate for treating prostate cancer, Bria-Pros+™, part of the Bria-OTS+ platform of cellular immunotherapies. GMP manufacturing of Bria-Pros+ will provide clinical supplies for planned clinical trial use. As presented at the Society for the Immunotherapy of Cancer (SITC) meeting 2023, the pre-clinical proof-of-concept data demonstrated both feasibility and efficacy of BriaCell's platform of cellular cancer vaccines overall, with specific emphasis on Bria-Pros+. BriaCell genetically engineers cancer cell lines to produce cytokines and co-stimulatory factors that significantly increase immune stimulation compared to the unmodified (parent) cancer cell lines. These cell lines also express patient-specific Human leukocyte antigens (HLA) alleles and potentially provide personalized off the shelf treatment.

On February 7, 2024, BriaCell announced strong clinical data in breast cancer patients, and reported another notable responder case. Disease control rate of 61% was observed in evaluable Phase 2 patients treated with the same formulation in BriaCell's pivotal Phase 3 study. Disease control rate of 50% in evaluable patients treated with the Phase 3 formulation who failed prior antibody-drug conjugate (ADC) therapy. Notable responder had failed 4 prior therapies including ADC therapy with metastatic liver tumor "no longer observed" following BriaCell treatment.

On March 7, 2024, BriaCell announced that it had received and executed a letter of intent with Paula Pohlmann, MD, MSc, PhD, Associate Professor, Department of Investigational Cancer Therapeutics and Breast Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX to advance the clinical development of Bria-OTS+ and Bria-PROS+, BriaCell's personalized off-the-shelf cellular cancer vaccines in advanced breast cancer and prostate cancer, respectively.

On April 9, 2024, BriaCell presented positive clinical data demonstrating unmatched progression-free-survival (PFS) and clinical efficacy in antibody-drug conjugate (ADC) resistant and central nervous system (CNS) metastatic breast cancer at two posters at the 2024 American Association for Cancer Research (AACR) Annual Meeting. Progression fee survival of 4.2 months reported in Phase 2 ADC resistant patients who received Bria-IMT™ pivotal Phase 3 formulation was twice that of controls in similar studies[1]. Progression-free-survival results were reinforced by larger number of prior treatments in Bria-IMT™ population than in comparable studies. Bria-IMT™ PFS compared favorably to patients' most recent treatment PFS in 48% of patients. Additionally, Clinical benefit rate of 56% was reported in evaluable patients. Finally, 71% intracranial objective response rate (iORR) was reported in heavily pretreated patients. Findings supported clinical efficacy of Bria-IMT™ and highlighted its significant potential in managing CNS metastatic disease in advanced breast cancer.

[1] Cortes J et al. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): a phase 3 open-label randomized study. Lancet (2011) 377: 914–23.

On April 10, 2024, BriaCell reported preclinical data showing strong anti-cancer activity of its next generation, personalized, off-the-shelf, cell-based breast and prostate cancer clinical candidates, Bria-OTS+™ and Bria-PROS+™, in a poster session during the 2024 AACR Annual Meeting.

Preclinical data showed that BriaCell's Bria-OTS+™ and Bria-PROS+™ effectively induced an anti-cancer immune response via multiple mechanisms including naïve helper and killer T cells, dendritic cells, and natural killer (NK) cells. BriaCell hypothesizes that the novel mechanisms of action may lead to strong anti-cancer activity in breast and prostate cancer patients.

On April 24, 2024, BriaCell announced an oral presentation on the clinical data of the randomized Phase 2 study evaluating Bria-IMT™ in patients with metastatic breast cancer at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting taking place May 31 – June 4 at McCormick Place, Chicago, IL. Principal Investigator and Professor of Oncology, Mayo Clinic, Saranya Chumsri, MD, provided the presentation.

Copies of the poster presentations and abstracts are posted on https://briacell.com/scientific- publications/.

On May 24, 2024, BriaCell announced doubling of progression-free-survival (PFS) and reported clinical benefit data at the 2024 American Society of Clinical Oncology (ASCO). 83% intracranial objective response rate (iORR) with Bria-IMT™ was reported in heavily pretreated advanced breast cancer patients with CNS metastases. Median progression free survival (PFS) of 4.1 months in ADC resistant patients - doubled the PFS of patients in similar studies [1,2, 3].

Clinical benefit rate of 55% in evaluable patients includes HR+, HER2+ and TNBC disease - much higher than comparable studies [1,2, 3].

On May 28, 2024, BriaCell announced a clinical supply agreement with BeiGene, Ltd. (NASDAQ: BGNE) ("BeiGene") to evaluate the safety and efficacy of Bria-OTS™, BriaCell's next generation immunotherapy, in combination with BeiGene's anti-PD-1 antibody, tislelizumab, for the treatment of advanced heavily pretreated metastatic breast cancer.

On May 30, 2024, BriaCell announced the initiation of a first-in-human, Phase 1/2 study evaluating safety and efficacy of Bria-OTS™, BriaCell's personalized off-the-shelf next generation immunotherapy, as monotherapy and in combination with PD-1 inhibitor tislelizumab, in metastatic breast cancer.

On June 3, 2024, BriaCell presented clinical efficacy data at the 2024 ASCO annual meeting. BriaCell doubled progression-free-survival (PFS) and clinical benefit rate vs historical results in the literature. Bria-IMT™ PFS compared favorably to PFS of most recent treatment in 48% of Antibody-Drug Conjugate (ADC) resistant patients. Therapy was well-tolerated with no Bria-IMT™ related discontinuations. Clinical data highlighted significant potential of Bria-IMT™ in advanced metastatic breast cancer. Superiority of selected Phase 3 regimen and formulation was confirmed. Oral presentation by Mayo Clinic Professor and Principal Investigator, Saranya Chumsri, MD, was performed.

Oral Presentation Summary

Abstract Number for Publication: 1022

Title: Outcomes of advanced/metastatic breast cancer (aMBC) treated with Bria-IMT™, an allogeneic whole cell immunotherapy.

Session Type and Title: Rapid Oral Abstract – Breast Cancer—Metastatic
Session Date and Time: 6/3/2024; 11:30 AM-1:00 PM CDT

This presentation details the results of BriaCell's randomized Phase 2 study of Bria-IMT™ in combination with retifanlimab, an immune checkpoint inhibitor (CPI). The goal of randomization was to compare whether administration of the CPI early, in the first cycle of therapy, or later, late in the second cycle of therapy, offered any advantage. Two different formulations of Bria-IMT™ were also evaluated; one treated with interferon gamma and one untreated.

The patients entering the study were very heavily pretreated and had failed multiple prior therapies as shown in the Table 1 below.

Table 1. Prior Therapies in the Bria-IMT™ Phase 2 Study

Previous Therapies	Number of Patients (%)
Antibody-Drug Conjugates (ADC)	23 (44%)
Immune Checkpoint Inhibitor (CPI)	11 (20%)
Cyclin-Dependent Kinase (CDK) 4/6 Inhibitors	34 (63%)

A total of 54 patients were included in the Phase 1/2 study. Nearly half of these had been treated previously with an antibody drug conjugate and had progressed in their disease following this treatment. Another 20% had failed a prior immune checkpoint inhibitor. Nearly 2/3 of the patients had failed therapy with a CDK 4/6 inhibitor. On average they had failed six prior therapy attempts.

In the Phase 2 portion of the study, there were 32 patients with 16 treated with CPI early and 16 treated with CPI late. There was no statistically significant difference in progression-free survival (PFS) two groups. However, a slight advantage in the CPI early group has led this to be the selected regimen for the Phase 3 study. In the entire Phase 1/2 experience, with 54 patients, the formulation not incubated with interferon gamma showed a statistically significant improvement in PFS. Therefore, this formulation was selected for the Phase 3 study. The data are shown in Figure 1.

Figure 1. Effect of treatment sequence and formulation on PFS

Clinical benefit was seen in 55% of evaluable patients across all subtypes of breast cancer as shown in Figure 2 below.

Figure 2: Objective Response Rate (ORR) and Clinical Benefit Rate (CBR) in the Bria-IMT™ Phase 1/2 Study

The progression free survival rate and the clinical benefit rate as well as the objective response rate were markedly higher than those of similar patients treated with the treatment of their physician's choice in other studies. Notably, "Treatment of Physician's Choice" (TPC) will be the comparator in the Phase 3 study of Bria-IMT™. This is noted in Table 2 below.

Table 2. Comparative PFS, ORR and CBR in Similar Patients

Study	Prior Lines of Therapy (median, range)	PFS (months)	ORR (%)	CBR (%)
BriaCell's Phase 2 study patients who received pivotal Phase 3 study formulation	**6 (2-13)**	**3.9**	**9.5***	**55***
BriaCell's ADC Resistant Phase 2 patients who received pivotal Phase 3 study formulation	**6 (3-13)**	**4.1**	**12****	**53****
Bardia, A. et. al. [1]	4 (2-14)	1.7	4	8
Tripathy D. et. al. [2]	≥4 in 91%	1.9	3	10
O'Shaughnessy J. et. al. non-TNBC [3]	5 (2-14)	2.3	4	7
O'Shaughnessy J. et. al. TNBC [3]	4 (2-10)	1.6	5	10

*Data is for evaluable patients, n=42 with 12 not evaluable.
** Data is for evaluable patients, n = 17 with 6 not evaluable.
References: Data is shown for the intent to treat population for the control group treated with treatment of physician's choice, which is the comparator in the BriaCell Phase 3 study
1. Bardia A, et al. J Clin Oncol. 2024 May 20;42(15):1738-1744.
2. Tripathy D, et al. JAMA Oncol. 2022 Nov 1;8(11):1700-1701. jamaoncol.2022.4346. PMID: 36136348. This paper describes patients with brain metastases.
3. O'Shaughnessy J, et al. Breast Cancer Res Treat. 2022 Sep;195(2):127-139.

For additional detailed information of the clinical data on the oral presentation, please visit https://briacell.com/scientific-publications/.

On July 18, 2024, BriaCell reported significantly higher PFS for its top responder patient in the Phase 2 study of BriaCell's Bria-IMT™ regimen in combination with an immune checkpoint inhibitor in metastatic breast cancer. The patient remains alive and she continues to receive BriaCell's treatment regimen.

On September 10, 2024, BriaCell announced that it received positive feedback from its Pre-Investigational New Drug Application ("Pre-IND") meeting with the FDA for Bria-PROS+™ in prostate cancer. As a result of the Pre-IND meeting, the FDA waived the animal toxicology and animal pharmacokinetic (PK) studies requirement for opening the IND, greatly simplifying the development pathway for Bria-PROS+™. Other areas of discussion included BriaCell's plan to initiate the Phase 1/2 study pending completion of standard manufacturing and testing requirements.

On September 11, 2024, BriaCell reported positive updated overall survival data in its Phase 2 clinical study of Bria-IMT™ in combination with a CPI in late stage metastatic breast cancer. Median overall survival of 15.6 months in Phase 2 Bria-IMT™ study patients treated in combination with immune checkpoint inhibitor was reported. Overall survival of 15.6 months compares favorably with 6.7-9.3 months reported for similar patients in the literature. The Company's ongoing Phase 3 study is investigating Bria-IMT™ in similar metastatic breast cancer population. No drug related discontinuations have been reported to date.

On September 12, 2024, the Company closed a registered direct offering for the purchase and sale of 12,325,000 common shares of the Company for aggregate gross proceeds of approximately $8.5 million before deducting placement agent fees and other offering expenses. In addition, the Company issued 616,250 placement agent warrants. The placement agent warrants have a term of five years commencing September 11, 2024, are exercisable commencing March 11, 2025, and have an exercise price of $0.8625 per common share.

On September 18, 2024, BriaCell announced FDA-Authorized expanded access policy for metastatic breast cancer patients. The FDA has authorized the Expanded Access Policy (EAP) to help metastatic breast cancer patients in need for novel treatments. Expanded access policy is expected to provide potential lifesaving Bria-IMT™ to those cancer patients in need beyond the scope of BriaCell's pivotal Phase 3 clinical trial.

On October 1, 2024, BriaCell reported 100% resolution of brain metastasis in breast cancer patient with “Eye-Bulging” tumor. Dramatic anti-tumor response included complete resolution of right temporal lobe brain metastasis in patient with “Eye-Bulging” metastatic breast cancer. Heavily pre-treated patient had failed 8 prior regimens including antibody-drug conjugate (ADC) therapy and continued to receive BriaCell treatment.

Figure 1: Bria-IMT™ regimen resulted in 100% resolution of tumor in the right temporal lobe region of the brain

As shown in Figure 1, the right temporal lobe lesion is no longer detectable on the images taken at 8 months and 11 months on the Bria-IMT™ combination regimen. The orbital lesion has continued to shrink markedly (Figure 2). In addition, her tumor markers (blood tests that correlate with the amount of tumor in the body) remain markedly decreased from her pre-treatment levels.

Figure 2: Bria-IMT™ regimen resulted in near complete resolution of breast cancer tumor in the right orbit (behind the eye)

On October 2, 2024, the Company closed a registered direct offering for the purchase and sale of 5,128,500 common shares of the Company and warrants to purchase up to an aggregate of 5,128,000 common shares of the Company for aggregate gross proceeds of approximately $5.0 million before deducting placement agent fees and other offering expenses (the “October 2024 Offering”). Each common share was sold together with one warrant to purchase one common share at a combined purchase price of $0.975. The warrants have an exercise price of $0.85 per share, and are immediately exercisable for a period of five years from grant date. In addition, the Company issued 256,425 placement agent warrants. The placement agent warrants are immediately exercisable for a period of five years from grant date at an exercise price of $1.21875.

ITEM 1A. RISK FACTORS

An investment in our securities involves a high degree of risk. An investor should carefully consider the risks described below as well as other information contained in this Annual Report on Form 10-K and our other reports filed with the U.S. Securities and Exchange Commission ("SEC"). The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our securities could decline, and investors in our company may lose all or part of their investment.

Risks Related to Our Business

We have a history of losses, may incur future losses and may not achieve profitability

BriaCell is a development stage immune-oncology biotechnology corporation that to date has not recorded any revenues from the sale of diagnostic or therapeutic products. Since incorporation, BriaCell has accumulated net losses and expects such losses to continue as it commences product and pre-clinical development and eventually enters into license agreements for its technology. We incurred net losses of $4,791,466 and $20,302,394 in the fiscal years ended 2024 and 2023, respectively. Management expects to continue to incur substantial operating losses unless and until such time as product sales generate sufficient revenues to fund continuing operations. BriaCell has neither a history of earnings nor has it paid any dividends, and it is unlikely to pay dividends or enjoy earnings in the immediate or foreseeable future.

There is substantial doubt about our ability to continue as a going concern

The Company has incurred significant losses since its inception, including net losses of $4,791,466 and $20,302,394 in the fiscal years ended 2024 and 2023, respectively, and an accumulated deficit of $85,443,697 and $80,652,231 as of July 31, 2024 and July 31, 2023, respectively. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The Company's continuation as a going concern is dependent upon its ability to generate positive cash flows from operations and to secure additional sources of equity and/or debt financing. Despite the Company's intent to fund operations through equity and debt financing arrangements, there is no assurance that such financing will be available on terms acceptable to the Company, if at all.

This going concern risk may materially limit our ability to raise additional funds through the issuance of new debt or equity or may adversely affect the terms upon which such capital may be available. The inability to obtain sufficient financing on acceptable terms could have a material adverse effect on the Company's financial condition, results of operations, and business prospects.

The Company is actively pursuing strategies to mitigate these risks, focusing on transitioning towards revenue generation from its existing product offerings and expanding its customer base. However, there can be no assurance that these efforts will prove successful or that the Company will achieve its intended financial stability. The failure to successfully address these going concern risks may materially and adversely affect the Company's business, financial condition, and results of operations. Investors should consider the substantial risks and uncertainties inherent in the Company's business before investing in the Company's securities.

We are a pre-revenue clinical stage company

The Company is developing novel technologies that may not be efficacious or safe. The Company expects to spend a significant amount of capital to fund research and development. As a result, the Company expects that its operating expenses will increase significantly and, consequently, it will need to generate significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it will be profitable. There can be no assurances that the intellectual property of BriaCell, or other technologies it may acquire, will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed. The Company will be undertaking additional laboratory studies or trials with respect to the intellectual property of BriaCell, and there can be no assurance that the results from such studies or trials will result in a commercially viable product or will not identify unwanted side effects.

We have an unproven market for our product candidates

The Company believes that the anticipated market for its potential products and technologies if successfully developed will continue to exist and expand. These assumptions may prove to be incorrect for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.

We may not succeed in adapting to and meeting the business needs associated with our anticipated growth

Anticipated growth in all areas of BriaCell's business is expected to continue to place a significant strain on its managerial, operational and technical resources. The Company expects operating expenses and staffing levels to increase in the future. To manage such growth, the Company must expand its operational and technical capabilities and manage its employee base while effectively administering multiple relationships with various third parties. There can be no assurance that the Company will be able to manage its expanding operations effectively. Any failure to implement cohesive management and operating systems, to add resources on a cost-effective basis or to properly manage the Company's expansion could have a material adverse effect on its business and results of operations.

BriaPro may not generate revenue as expected

We are a majority shareholder of BriaPro. BriaPro may not generate financial returns or may not yield the desired business outcome. The success of our investment in a company is sometimes dependent on the availability of additional funding on favorable terms or a liquidity event such as an initial public offering. We may record impairment charges in relation to our strategic investments which will have a negative impact on our financial position.

This may expose us to additional reputational, financial, legal, compliance or operational risks. This could impact our return on our investment. In the event BriaPro fails to generate revenue, this may erode or dilute its value to our shareholders.

We are heavily reliant on third-parties to carry out a large portion of our business

The Company does not expect to have any in-house manufacturing, pharmaceutical development or marketing capability. To be successful, a product must be manufactured and packaged in commercial quantities in compliance with regulatory requirements and in reasonable time frames and at accepted costs. The Company intends to contract with third parties to develop its products. No assurance can be given that the Company or its suppliers will be able to meet the supply requirements in respect of the product development or commercial sales.

Production of therapeutic products may require raw materials for which the sources and amount of supply are limited, or may be hindered by quality or scheduling issues in respect of the third party suppliers over which the Company has limited control. An inability to obtain adequate supplies of raw materials could significantly delay the development, regulatory approval and marketing of a product. The Company has limited in-house personnel to internally manage all aspects of product development, including the management of multi-center clinical trials. The Company is significantly reliant on third-party consultants and contractors to provide the requisite advice and management. There can be no assurance that the clinical trials and product development will not encounter delays which could adversely affect prospects for the Company's success.

To be successful, an approved product must also be successfully marketed. The market for the Company's product being developed by the Company may be large and will require substantial sales and marketing capability. At the present time, the Company does not have any internal capability to market pharmaceutical products. The Company intends to enter into one or more strategic partnerships or collaborative arrangements with pharmaceutical companies or other companies with marketing and distribution expertise to address this need. If necessary, the Company will establish arrangements with various partners for geographical areas. There can be no assurance that the Company can market, or can enter into a satisfactory arrangement with a third party to market a product in a manner that would assure its acceptance in the marketplace. However, if a satisfactory arrangement with a third party to market and/or distribute a product is obtained; the Company will be dependent on the corporate collaborator(s) who may not devote sufficient time, resources and attention to the Company's programs, which may hinder efforts to market the products.

Should the Company not establish marketing and distribution strategic partnerships and collaborative arrangements on acceptable terms, and undertake some or all of those functions, the Company will require significant additional human and financial resources and expertise to undertake these activities, the availability of which is not guaranteed. The Company will rely on third parties for the timely supply of raw materials, equipment, contract manufacturing, and formulation or packaging services. Although the Company intends to manage these third-party relationships to ensure continuity and quality, some events beyond the Company's control could result in complete or partial failure of these goods and services. Any such failure could have a material adverse effect on the financial conditions and result of operation of the Company.

Due to the complexity of the process of developing pharmaceutical products, the Company's business may depend on arrangements with pharmaceutical and biotechnology companies, corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, technology rights, manufacturing, marketing and commercialization of its products. Such agreements could obligate the Company to diligently bring potential products to market, make milestone payments and royalties that, in some instances, could be substantial, and incur the costs of filing and prosecuting patent applications. There can be no assurance that the Company will be able to establish or maintain collaborations that are important to its business on favorable terms, or at all.

A number of risks arise from the Company's potential dependence on collaborative agreements with third parties. Product development and commercialization efforts could be adversely affected if any collaborative partner terminates or suspends its agreement with the Company, causes delays, fails to on a timely basis develop or manufacture in adequate quantities a substance needed in order to conduct clinical trials, fails to adequately perform clinical trials, determines not to develop, manufacture or commercialize a product to which it has rights, or otherwise fails to meet its contractual obligations. The Company's collaborative partners could pursue other technologies or develop alternative products that could compete with the products the Company is developing.

The Company has signed Non-Disclosure Agreements ("NDA") with many different third parties. As is customary in the industry. There is no guarantee that, despite the terms of the NDA which bind third parties, the Company will ultimately be able to prevent from such third parties from breaching their obligations under the NDA. Use of the Company's confidential information in an unauthorized manner is likely to negatively affect the Company.

Pre-clinical studies and initial clinical trials are not necessarily predictive of future results

Pre-clinical tests and Phase 1/2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in pre-clinical and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. Favorable results in early trials may not be repeated in later trials.

A number of companies in the life sciences industry have suffered significant setbacks in advanced clinical trials, even after positive results in earlier trials. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed, repeated or terminated. Any pre-clinical data and the clinical results obtained for BriaCell's technology may not predict results from studies in larger numbers of subjects drawn from more diverse populations or in the commercial setting, and also may not predict the ability of our products to achieve their intended goals, or to do so safely.

An inability to obtain raw materials or product supply could have a material adverse effect on the Company's business, financial condition and results of operations

Raw materials and supplies are generally available in quantities to meet the needs of the Company's business. The Company will be dependent on third-party manufacturers for the pharmaceutical products that it markets An inability to obtain raw materials or product supply could have a material adverse impact on the Company's business, financial condition and results of operations.

We must obtain additional capital to continue our operations

The Company anticipates that additional capital will be required to complete its current research and development programs. It is anticipated that future research, additional pre-clinical and toxicology studies and manufacturing initiatives, including to prepare for market approval and successful product market launch, will require additional funds. Further financing may dilute the current holdings of shareholders and may thereby result in a loss for the shareholders. There can be no assurance that the Company will be able to obtain adequate financing, or financing on terms that are reasonable or acceptable for these or other purposes, or to fulfill the Company's obligations under various license agreements. Failure to obtain such additional financing could result in delay or indefinite postponement of further research and development of the Company's technologies with the possible loss of license rights to these technologies.

We are highly dependent on our key personnel

Although the Company is expected to have experienced senior management and personnel, the Company will be substantially dependent upon the services of a few key personnel, particularly Dr. William V. Williams, Dr. Giuseppe Del Priore, Dr. Miguel Lopez-Lago and other professionals for the successful operation of its business. Pivotal Phase 3 of Bria-IMT™ regimen with an immune check point inhibitor, and Phase 1/2 study of Bria-OTS ™, and the Company's research and product development is planned to be completed by qualified professionals and is expected to concentrate on treatment of advanced breast cancer and prostate cancer. The loss of the services of any of these personnel could have a material adverse effect on the business of the Company. The Company may not be able to attract and retain personnel on acceptable terms given the intense competition for such personnel among high technology enterprises, including biotechnology and healthcare companies, universities and non-profit research institutions. If we lose any of these persons, or are unable to attract and retain qualified personnel, our business, financial condition and results of operations may be materially and adversely affected.

BriaCell in the future may acquire businesses, products or technologies that it believes complement or expand its existing business.

Acquisitions of this type involve a number of risks, including the possibility that the operations of the acquired business will not be profitable or that the attention of the Company's management will be diverted from the day-to-day operation of its business. An unsuccessful acquisition could reduce the Company's margins or otherwise harm its financial condition.

If the Company experiences a data security breach and confidential information is disclosed, the Company may be subject to penalties and experience negative publicity

The Company and its customers could suffer harm if personal and health information were accessed by third parties due to a system security failure. The collection of data requires the Company to receive and store a large amount of personally de-identifiable data. Recently, data security breaches suffered by well-known companies and institutions have attracted a substantial amount of media attention, prompting legislative proposals addressing data privacy and security. The Company may become exposed to potential liabilities with respect to the data that it collects, manages and processes, and may incur legal costs if information security policies and procedures are not effective or if the Company is required to defend its methods of collection, processing and storage of personal data. Future investigations, lawsuits or adverse publicity relating to its methods of handling such information could have a material adverse effect on the Company's business, financial condition and results of operations due to the costs and negative market reaction relating to such developments.

We may not succeed in completing the development of our products, commercializing our products or generating significant revenues

Since commencing our operations, we have focused on the research and development and limited clinical trials of our product candidates. Our ability to generate revenues and achieve profitability depends on our ability to successfully complete the development of our products, obtain market approval and generate significant revenues. The future success of our business cannot be determined at this time, and we do not anticipate generating revenues from product sales for the foreseeable future. In addition, we face a number of challenges with respect to our future commercialization efforts, including, among others, that:

- we may not have adequate financial or other resources to complete the development of our product, including two stages of clinical development that are necessary in order to commercialize our products;
- we may not be able to manufacture our products in commercial quantities, at an adequate quality or at an acceptable cost;
- we may not be able to maintain our CE mark due to regulatory changes;
- we may never receive FDA or Health Canada approval for our intended development plans;
- we may not be able to establish adequate sales, marketing and distribution channels;
- healthcare professionals and patients may not accept our product candidates;
- technological breakthroughs in cancer detection, treatment and prevention may reduce the demand for our product candidates;
- changes in the market for cancer treatment, new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- third-party payors may not agree to reimburse patients for any or all of the purchase price of our products, which may adversely affect patients' willingness to purchase our product candidates;
- uncertainty as to market demand may result in inefficient pricing of our product candidates;
- we may face third-party claims of intellectual property infringement;
- we may fail to obtain or maintain regulatory approvals for our products candidates in our target markets or may face adverse regulatory or legal actions relating to our product candidates even if regulatory approval is obtained; and
- we are dependent upon the results of ongoing clinical studies relating to our product candidates and the products of our competitors. We may fail in obtaining positive results.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our product candidates could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

If product liability lawsuits are brought against us, we may incur substantial liabilities and the commercialization of our drug candidates may be affected

As our drug candidates are currently in clinical trials, we face an inherent risk of product liability suits and will face an even greater risk if we obtain approval to commercialize any drugs. For example, we may be sued if our drug candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the drug, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our drug candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our drugs;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any drug candidate; and
- a decline in the price of our common shares.

We believe that we currently have appropriate insurance covering clinical trials. However, it may transpire that the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Any inability to maintain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of drugs we develop, alone or with collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Additionally, we may be sued if the products that we commercialize, market or sell cause or are perceived to cause injury or are found to be otherwise unsuitable, and may result in:

- decreased demand for those products;
- damage to our reputation;
- costs incurred related to product recalls;
- limiting our opportunities to enter into future commercial partnerships; and
- a decline in the price of our common shares.

Global economic uncertainty and financial market volatility caused by political instability, changes in international trade relationships and conflicts, such as the conflict between Russia and Ukraine and rising tensions in the Middle East, could make it more difficult for us to access financing and could adversely affect our business and operations.

Our ability to raise capital is subject to the risk of adverse changes in the market value of our stock. Periods of macroeconomic weakness or recession and heightened market volatility caused by adverse geopolitical developments could increase these risks, potentially resulting in adverse impacts on our ability to raise further capital on favorable terms. The impact of geopolitical tension, such as the war in the Middle East, a deterioration in the bilateral relationship between the US and China or an escalation in conflict between Russia and Ukraine, including any resulting sanctions, export controls or other restrictive actions that may be imposed by the US and/or other countries against governmental or other entities in, for example, Russia, also could lead to disruption, instability and volatility in global trade patterns, which may in turn impact our ability to source necessary reagents, raw materials and other inputs for our research and development operations.

We may be adversely affected by the effects of inflation.

Inflation has the potential to adversely affect our business, results of operations, financial position and liquidity by increasing our overall cost structure, particularly if we are unable to achieve commensurate increases in the prices we charge our customers. The existence of inflation in the economy has the potential to result in higher interest rates and capital costs, supply shortages, increased costs of labor and other similar effects. As a result of inflation, we may experience increases in the costs of labor, materials, and other inputs, such as engineering consultants. Although we may take measures to mitigate the impact of this inflation, if these measures are not effective our business, results of operations, financial position and liquidity could be materially adversely affected. Even if such measures are effective, there could be a difference between the timing of when these beneficial actions impact our results of operations and when the cost inflation is incurred.

A material breach in security relating to the Company's information systems and regulation related to such breaches, cyber-attacks, or other disruptions could adversely affect the Company, expose us to liability and affect our business and reputation.

Information security risks have generally increased in recent years, in part because of the proliferation of new technologies and the use of the Internet, and the increased sophistication and activity of organized crime, hackers, terrorists, activists, cybercriminals and other external parties, some of which may be linked to terrorist organizations or hostile foreign governments. Cybersecurity attacks are becoming more sophisticated and include malicious software, ransomware, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in critical systems, unauthorized release of confidential or otherwise protected information and corruption of data, substantially damaging the Company's reputation. Any person who circumvents the security measures could steal proprietary or confidential customer information or cause interruptions in the Company's operations.

We are increasingly dependent on our information technology systems and infrastructure for our business. We, our collaborators and our service providers collect, store, and transmit sensitive information including intellectual property, proprietary business information, and personal information in connection with our business operations. The secure maintenance of this information is critical to our operations and business strategy. Some of this information could be an attractive target of criminal attack by third parties with a wide range of motives and expertise, including organized criminal groups, "hacktivists," disgruntled current or former employees, nation-state and nation-state supported actors, and others. Cyber-attacks are of ever-increasing levels of sophistication, and despite our security measures, our information technology and infrastructure may be vulnerable to such attacks or may be breached, including due to employee error or malfeasance.

We have implemented information security measures to protect our systems, proprietary information, and sensitive data against the risk of inappropriate and unauthorized external use and disclosure and other types of compromise. However, despite these measures, and due to the ever-changing information cyber-threat landscape, we cannot guarantee that these measures will be adequate to detect, prevent or mitigate security breaches and other incidents and we may be subject to data breaches through cyber-attacks, malicious code (such as viruses and worms), phishing attacks, social engineering schemes, and insider theft or misuse. Any such breach could compromise our networks and the information stored there could be accessed, modified, destroyed, publicly disclosed, lost or stolen. If our systems become compromised, we may not promptly discover the intrusion.

Any security breach or other incident, whether real or perceived, could cause us to suffer reputational damage. Such incidents could result in costs to respond to, investigate and remedy such incidents, notification obligations to affected individuals, government agencies, credit reporting agencies and other third parties, legal claims or proceedings, and liability under our contracts with other parties and federal and state laws that protect the privacy and security of personal information. The Company's failure to prevent security breaches, or well-publicized security breaches affecting the Internet in general, could significantly harm the Company's reputation and business and financial results.

Risks Related to Our Intellectual Property

We may not successfully develop, maintain and protect our proprietary products and technologies

BriaCell's success depends to a significant degree upon its ability to develop, maintain and protect proprietary products and technologies. BriaCell files patent applications in the United States and other countries as part of its global strategy to protect its intellectual property and maintains certain U.S. and Non-U.S. patents in its intellectual property portfolio. However, patents provide only limited protection of BriaCell's intellectual property. The assertion of patent protection involves complex legal and factual determinations and is therefore uncertain and can be expensive. BriaCell cannot provide assurances that patents will be granted with respect to any of its pending patent applications, or that the scope of any of its granted patents, or any patents granted in the future, will be sufficiently broad to offer meaningful protection, or that it will develop and file patent applications on additional proprietary technologies that are patentable, or, if patentable, that any patents will be granted from such patent applications. BriaCell's current or future patents could be successfully challenged, invalidated or circumvented. This could result in BriaCell's patent rights failing to create an effective competitive barrier. Losing a significant patent or failing to get a patent to issue from a pending patent application that BriaCell considers significant could have a material adverse effect on BriaCell's business. The laws governing the scope of patent coverage in various countries continue to evolve. The laws of some foreign countries may not protect BriaCell's intellectual property rights to the same extent as the laws of the United States. BriaCell has applied for patent protection only in selected countries. Therefore, third parties may be able to replicate BriaCell technologies covered by BriaCell's patent portfolio in countries in which it does not have patent protection.

BriaCell's future success and competitive position depends in part upon its ability to maintain its intellectual property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications.

We are susceptible to intellectual property suits that could cause us to incur substantial costs or pay substantial damages or prohibit us from selling our product candidates

There is a substantial amount of litigation over patent and other intellectual property rights in the biotechnology industry. Whether or not a product infringes a patent involves complex legal and factual considerations, the determination of which is often uncertain. Our management is presently unaware of any other parties' patents and proprietary rights which our products under development would infringe. Searches typically performed to identify potentially infringed patents of third parties are often not conclusive and, because patent applications can take many years to issue, there may be applications now pending, which may later result in issued patents which our current or future products may infringe or be alleged to infringe. In addition, our competitors or other parties may assert that our product candidates and the methods employed may be covered by patents held by them. If any of our products infringes a valid patent, we could be prevented from manufacturing or selling such product unless we are able to obtain a license or able to redesign the product in such a manner as to avoid infringement. A license may not always be available or may require us to pay substantial royalties. We also may not be successful in any attempt to redesign our product to avoid infringement, nor does a later redesign protect BriaCell from prior infringement. Infringement and other intellectual property claims, with or without merit, can be expensive and time-consuming to litigate and can divert our management's attention from operating our business.

The steps we have taken to protect our intellectual property may not be adequate, which could have a material adverse effect on our ability to compete in the market

BriaCell's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of BriaCell's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. In addition to filing patent applications, we rely on confidentiality, non-compete, non-disclosure and assignment of inventions provisions, as appropriate, in our agreements with our employees, consultants, and service providers, to protect and otherwise seek to control access to, and distribution of, our proprietary information. These measures may not be adequate to protect our intellectual property from unauthorized disclosure, third-party infringement or misappropriation, for the following reasons:

- the agreements may be breached, may not provide the scope of protection we believe they provide or may be determined to be unenforceable;
- we may have inadequate remedies for any breach;
- proprietary information could be disclosed to our competitors; or
- others may independently develop substantially equivalent or superior proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technologies.

Specifically, with respect to non-compete agreements, both state law and precedent varies greatly from state to state and we may be unable to enforce these agreements, in whole or in part, and it may be difficult for us to restrict our competitors from gaining the expertise that our former employees gained while working for us. If our intellectual property is disclosed or misappropriated, it could harm our ability to protect our rights and could have a material adverse effect on our business, financial condition and results of operations.

We may need to initiate lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would harm our ability to compete in the market

We rely on patents, confidentiality and trade secrets to protect a portion of our intellectual property and our competitive position. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in the biotechnology/ pharmaceutical industry can be uncertain. In order to protect or enforce our patent rights, we may initiate patent and related litigation against third parties, such as infringement suits or requests for injunctive relief. BriaCell's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of BriaCell's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Any lawsuits that we initiate could be expensive, take significant time and divert our management's attention from other business concerns and the outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, or adversely affect its ability to distribute any products that are subject to such litigation. In addition, we may provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, including attorney fees, if any, may not be commercially valuable. The occurrence of any of these events could have a material adverse effect on our business, financial condition and results of operations.

We may be subject to damages resulting from claims that we or our employees or contractors have wrongfully used or disclosed alleged trade secrets of their former employers

Many of our employees and contractors were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or any employee or contractor have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of his or her former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain therapeutic candidates, which could severely harm our business, financial condition and results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our products that receive marketing approval, or such authorities do not grant our products appropriate periods of exclusivity before approving generic versions of our products, the sales of our products could be adversely affected.

Once a new drug application is approved, the product covered thereby becomes a "reference listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference listed drugs through submission of abbreviated new drug applications in the United States. In support of an abbreviated new drug applications, a generic manufacturer need not conduct clinical trials. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference listed drug and that the generic version is bioequivalent to the reference listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference listed drug is typically lost to the generic product.

The FDA may not approve abbreviated new drug applications for a generic product until any applicable period of non-patent exclusivity for the reference listed drug has expired. The United States Federal Food, Drug, and Cosmetic Act provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity ("NCE"). Specifically, in cases where such exclusivity has been granted, abbreviated new drug applications may not be submitted to the FDA until the expiration of five years, unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference listed drug.

While we believe that our products contain active ingredients that would be treated as NCEs by the FDA and, therefore, if approved, should be afforded five years of data exclusivity, the FDA may disagree with that conclusion and may approve generic products after a period that is less than five years. If the FDA were to award NCE exclusivity to someone other than us, we believe that we would still be awarded three year "Other" exclusivity protection from generic competition, which is awarded when an application or supplement contains reports of new clinical investigations (not bioavailability studies) conducted or sponsored by an applicant and essential for approval. Manufacturers may seek to launch these generic products following the expiration of the applicable marketing exclusivity period, even if we still have patent protection for our product. If we do not maintain patent protection and data exclusivity for our product candidates, our business may be materially harmed.

Competition that our products may face from generic versions of our products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we have made in those product candidates.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Risks Related to Regulations

Changes in legislation and regulations may affect our revenue and profitability

Existing and proposed changes in the laws and regulations affecting public companies may cause the Company to incur increased costs as the Company evaluates the implications of new rules and responds to new requirements. Failure to comply with new rules and regulations could result in enforcement actions or the assessment of other penalties. New laws and regulations could make it more difficult to obtain certain types of insurance, including director's and officer's liability insurance, and the Company may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage, to the extent that such coverage remains available.

The impact of these events could also make it more difficult for the Company to attract and retain qualified persons to serve on the Board, or as executive officers. The Company may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause the Company's general and administrative costs to increase beyond what the Company currently has planned. Although the Company evaluates and monitors developments with respect to new rules and laws, the Company cannot predict or estimate the amount of the additional costs the Company may incur or the timing of such costs with respect to such evaluations and/or compliance and cannot provide assurances that such additional costs will render the Company compliant with such new rules and laws.

If we or our licensees are unable to obtain U.S., Canadian and/or foreign regulatory approval for our product candidates, we will be unable to commercialize our therapeutic candidates

To date, we have not marketed, distributed or sold an approved product. Our therapeutic candidates are subject to extensive governmental regulations relating to development, clinical trials, manufacturing and commercialization of drugs. We may not obtain marketing approval for any of our therapeutic candidates in a timely manner or at all. In connection with the clinical trials for our product candidates and other therapeutic candidates that we may seek to develop in the future, either on our own or throughout licensing arrangements, we face the risk that:

- a product candidate may not prove safe or efficacious;
- the results with respect to any product candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA, Health Canada or other regulatory authorities; and
- the results will justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of the therapeutic candidate.

Any delay or failure in obtaining the required regulatory approvals will materially and adversely affect our ability to generate future revenues from a particular product candidate. Any regulatory approval to market a product may be subject to limitations on the indicated uses for which we may market the product or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the product. We and our licensees, as applicable, also are, and will be, subject to numerous foreign regulatory requirements that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process includes all of the risks associated with the FDA approval process that we describe above, as well as risks attributable to the satisfaction of foreign requirements. Approval by the FDA does not ensure approval by regulatory authorities outside the United States. Foreign jurisdictions may have different approval processes than those required by the FDA and may impose additional testing requirements for our therapeutic candidates.

If the third parties on which we rely to conduct our clinical trials and clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for, or commercialize, our product candidates

We do not have the ability to independently conduct our clinical trials for our product candidates and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory clearance for, or successfully commercialize, our product candidates on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

Modifications to our product candidates, or to any other product candidates that we may develop in the future, may require new regulatory clearances or approvals or may require us or our licensees, as applicable, to recall or cease marketing these therapeutic candidates until clearances are obtained

Modifications to our product candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product that we may develop in the future, may require new regulatory clearance, or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA requires pharmaceutical products manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable regulations and guidelines that a modification may be implemented without pre-clearance by the FDA; however, the FDA can review a manufacturer's decision and may disagree. The FDA may also on its own initiative determine that a new clearance or approval is required. If the FDA requires new clearances or approvals of any pharmaceutical product or medical device for which we or our licensees receive marketing approval, if any, we or our licensees may be required to recall such product and to stop marketing the product as modified, which could require us or our licensees to redesign the product and will have a material adverse effect on our business, financial condition and results of operations. In these circumstances, we may be subject to significant enforcement actions.

The results of our clinical trials may not support our product claims or may result in the discovery of adverse side effects

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our product claims or that any regulatory authority whose approval we will require in order to market and sell our products in any territory will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that clinical trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for the proposed indicated uses, which could cause us to abandon a product and may delay development of others. Any delay or termination of our clinical trials will delay the filing of our regulatory submissions and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile.

Clinical trials involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results

We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including FDA approval. Clinical trials are expensive and complex, can take many years and have uncertain outcomes. We cannot predict whether we or our licensees will encounter problems with any of the completed, ongoing or planned clinical trials that will cause us, our licensees or regulatory authorities to delay or suspend clinical trials, or delay the analysis of data from completed or ongoing clinical trials. We estimate that clinical trials of our most advanced therapeutic candidates will continue for several years, but they may take significantly longer to complete. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future therapeutic candidates, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;

- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- slower than anticipated patient recruitment and enrollment;
- negative or inconclusive results from clinical trials;
- unforeseen safety issues;
- uncertain dosing issues;
- an inability to monitor patients adequately during or after treatment; and
- problems with investigator or patient compliance with the trial protocols.

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. Despite the results reported in earlier clinical trials for our therapeutic candidates, we do not know whether any Phase 3 or other clinical trials we or our licensees may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our therapeutic candidates. If later-stage clinical trials of any therapeutic candidate do not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which will have a material adverse effect on our business, financial condition and results of operations.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement and access to drugs, which could adversely affect our future revenues and profitability

To the extent our products are developed, commercialized, and successfully introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Globally, governmental and other third-party payors are becoming increasingly aggressive in attempting to contain health care costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue.

In the U.S., we are subject to substantial pricing, reimbursement, and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Affordable Care Act instituted comprehensive health care reform, and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions), and impose new and/or increased taxes. The future of the Affordable Care Act and its constituent parts are uncertain at this time.

In almost all markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe and in other countries is and will be determined by national regulatory authorities. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides, and that treatment with the product works at least as well as currently available treatments.

The continuing efforts of government and insurance companies, health maintenance organizations, and other payors of health care costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers, and collaborative partners, as well as the availability of capital.

United States federal and state privacy laws, and equivalent laws of other nations, may increase our costs of operation and expose us to civil and criminal sanctions

HIPPA, and the regulations that have been issued under it, and similar laws outside the United States, contains substantial restrictions and requirements with respect to the use and disclosure of individuals' protected health information. The HIPAA privacy rules prohibit "covered entities," such as healthcare providers and health plans, from using or disclosing an individual's protected health information, unless the use or disclosure is authorized by the individual or is specifically required or permitted under the privacy rules. Under the HIPAA security rules, covered entities must establish administrative, physical and technical safeguards to protect the confidentiality, integrity and availability of electronic protected health information maintained or transmitted by them or by others on their behalf. While we do not believe that we will be a covered entity under HIPAA, we believe many of our customers will be covered entities subject to HIPAA. Such customers may require us to enter into business associate agreements, which will obligate us to safeguard certain health information we obtain in the course of our relationship with them, restrict the manner in which we use and disclose such information and impose liability on us for failure to meet our contractual obligations.

In addition, under HITECH, which was signed into law as part of the U.S. stimulus package in February 2009, certain of HIPAA's privacy and security requirements are now also directly applicable to "business associates" of covered entities and subject them to direct governmental enforcement for failure to comply with these requirements. We may be deemed as a "business associate" of some of our customers. As a result, we may be subject as a "business associate" to civil and criminal penalties for failure to comply with applicable privacy and security rule requirements. Moreover, HITECH created a new requirement obligating "business associates" to report any breach of unsecured, individually identifiable health information to their covered entity customers and imposes penalties for failing to do so.

In addition to HIPAA, most U.S. states have enacted patient confidentiality laws that protect against the disclosure of confidential medical information, and many U.S. states have adopted or are considering adopting further legislation in this area, including privacy safeguards, security standards, and data security breach notification requirements. These U.S. state laws, which may be even more stringent than the HIPAA requirements, are not supplanted by the federal requirements, and we are therefore required to comply with them to the extent they are applicable to our operations.

These and other possible changes to HIPAA or other U.S. federal or state laws or regulations, or comparable laws and regulations in countries where we conduct business, could affect our business and the costs of compliance could be significant. Failure by us to comply with any of the standards regarding patient privacy, identity theft prevention and detection, and data security may subject us to penalties, including civil monetary penalties and in some circumstances, criminal penalties. In addition, such failure may damage our reputation and adversely affect our ability to retain customers and attract new customers.

The protection of personal data, particularly patient data, is subject to strict laws and regulations in many countries. The collection and use of personal health data in the E.U. is governed by the provisions of Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (the "Data Protection Directive"). The Data Protection Directive imposes a number of requirements, including an obligation to seek the consent of individuals to whom the personal data relates, the information that must be provided to the individuals, notification of data processing obligations to the competent national data protection authorities of individual E.U. member states and the security and confidentiality of the personal data. The Data Protection Directive also imposes strict rules on the transfer of personal data out of the E.U. to the U.S.. Failure to comply with the requirements of the Data Protection Directive and the related national data protection laws of the E.U. member states may result in fines and other administrative penalties and harm our business. We may incur extensive costs in ensuring compliance with these laws and regulations, particularly if we are considered to be a data controller within the meaning of the Data Protection Directive.

If we fail to comply with the U.S. federal Anti-Kickback Statute and similar state and foreign country laws, we could be subject to criminal and civil penalties and exclusion from federally funded healthcare programs including the Medicare and Medicaid programs and equivalent third country programs, which would have a material adverse effect on our business and results of operations

A provision of the Social Security Act, commonly referred to as the federal Anti-Kickback Statute, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, directly or indirectly, in cash or in kind, to induce or reward the referring, ordering, leasing, purchasing or arranging for, or recommending the ordering, purchasing or leasing of, items or services payable, in whole or in part, by Medicare, Medicaid or any other federal healthcare program. Although there are a number of statutory exemptions and regulatory safe harbors to the federal Anti-Kickback Statute protecting certain common business arrangements and activities from prosecution or regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that do not fit squarely within an exemption or safe harbor may be subject to scrutiny. The federal Anti-Kickback Statute is very broad in scope and many of its provisions have not been uniformly or definitively interpreted by existing case law or regulations. In addition, most of the states have adopted laws similar to the federal Anti-Kickback Statute, and some of these laws are even broader than the federal Anti-Kickback Statute in that their prohibitions may apply to items or services reimbursed under Medicaid and other state programs or, in several states, apply regardless of the source of payment. Violations of the federal Anti-Kickback Statute may result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

All of our future financial relationships with U.S. healthcare providers, purchasers, formulary managers, and others who provide products or services to federal healthcare program beneficiaries will potentially be governed by the federal Anti-Kickback Statute and similar state laws. We believe our operations will be in compliance with the federal Anti-Kickback Statute and similar state laws. However, we cannot be certain that we will not be subject to investigations or litigation alleging violations of these laws, which could be time-consuming and costly to us and could divert management's attention from operating our business, which in turn could have a material adverse effect on our business. In addition, if our arrangements were found to violate the federal Anti-Kickback Statute or similar state laws, the consequences of such violations would likely have a material adverse effect on our business, results of operations and financial condition.

There are other federal and state laws that may affect our ability to operate, including the federal civil False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. Moreover, we may be subject to other federal false claim laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs. Moreover, there are analogous state laws. Violations of these laws can result in substantial criminal, civil or administrative penalties, damages, fines and exclusion from participation in federal healthcare programs.

Moreover, the provisions of the Foreign Corrupt Practices Act of 1997 and other similar anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from providing money or anything of value to officials of foreign governments, foreign political parties, or international organizations with the intent to obtain or retain business or seek a business advantage. Recently, there has been a substantial increase in anti-bribery law enforcement activity by U.S. regulators, with more aggressive and frequent investigations and enforcement by both the SEC and the Department of Justice. A determination that our operations or activities violated U.S. or foreign laws or regulations could result in imposition of substantial fines, interruption of business, loss of supplier, vendor or other third-party relationships, termination of necessary licenses and permits, and other legal or equitable sanctions. In addition, lawsuits brought by private litigants may also follow as a consequence.

In both domestic and foreign markets, the development, formulation, manufacturing, packaging, labeling, handling, distribution, import, export, licensing, sale and storage of pharmaceuticals and medical devices are affected by a body of laws, governmental regulations, administrative determinations, including those by Health Canada and the FDA, court decisions and similar constraints.

Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of government in foreign jurisdictions. There can be no assurance that the Company and the Company's partners are in compliance with all of these laws, regulations and other constraints. The Company and its partners may be required to incur significant costs to comply with such laws and regulations in the future, and such laws and regulations may have an adverse effect on the business. The failure of the Company or its partners to comply with current or future regulatory requirements could lead to the imposition of significant penalties or claims and may have a material adverse effect on the business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead the Company and its partners to discontinue product development and could have an adverse effect on the business.

The Company's international operations expose it and its representatives, agents and distributors to risks inherent to operating in foreign jurisdictions that could materially adversely affect its operations and financial position.

These risks include:

- country specific taxation policies;
- imposition of additional foreign governmental controls or regulations;
- export license requirements;
- changes in tariffs and other trade restrictions; and
- complexity of collecting receivables in a foreign jurisdiction.

Moreover, applicable agreements relating to business in foreign jurisdictions are governed by foreign laws and are subject to dispute resolution in the courts of, or through arbitration proceedings in, the country or region in which the parties are located or another jurisdiction agreed upon by the parties. The Company cannot accurately predict whether such jurisdictions will provide an effective and efficient means of resolving disputes that may arise in the future. Even if it obtains a satisfactory decision through arbitration or a court proceeding, the Company could have difficulty in enforcing any award or judgment on a timely basis or at all.

Risks Related to Our Securities

If we are not able to comply with the applicable continued listing requirements or standards of the TSX Exchange or Nasdaq, TSX Exchange or Nasdaq could delist our common shares

In order to maintain the listing of our common shares on the TSX Exchange and the Nasdaq Capital Market, we must satisfy minimum financial and other continued listing requirements and standards, including those regarding director independence and independent committee requirements, minimum stockholders' equity, minimum share price, and certain corporate governance requirements. There can be no assurances that we will be able to comply with such applicable listing standards.

On July 3, 2024, the Company received a letter from the Listing Qualifications Department of Nasdaq indicating that, based upon the Company's Market Value of Listed Securities ("MVLS") for the 33 consecutive business days from May 15, 2024, to July 2, 2024, the Company did not meet the minimum MVLS of $35,000,000 required for continued listing on Nasdaq pursuant to Nasdaq Listing Rule 5550(b)(2). The letter also indicated that the Company will be provided with the Compliance Period of 180 calendar days, or until December 30, 2024, in which to regain compliance pursuant to Nasdaq Listing Rule 5810(c)(3)(C). If we regain compliance with the MVLS, Nasdaq will provide written confirmation to us and close the matter.

In the event that we do not regain compliance prior to the end of the compliance period, we will receive written notification that our securities are subject to delisting, at which point we may appeal the delisting determination.

In addition, on August 22, 2024, the Company received a letter from the Nasdaq Listing Qualifications Department notifying the Company that, for the last 30 consecutive business days, the closing bid price for the Company's common shares have been below the minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement").

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has been given 180 calendar days, or until February 18, 2025, to regain compliance with the Minimum Bid Price Requirement.

If the Company does not regain compliance with the Minimum Bid Price Requirement by February 18, 2025, the Company may be afforded a second 180 calendar day period to regain compliance. To qualify, the Company will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market (which the Company currently does not meet) with the exception of the Minimum Bid Price Requirement and will need to provide written notice of its intention to cure the deficiency during such additional compliance period, by effecting a reverse split of its common shares, if necessary. If it appears to the Staff that the Company will not be able to cure the deficiency, or if the Company is otherwise not eligible for the additional compliance period, and the Company does not regain compliance by February 18, 2025, Nasdaq will provide written notification to the Company that its common shares are subject to delisting. At that time, the Company may appeal the delisting determination to a hearings panel pursuant to the procedures set forth in the applicable Nasdaq Listing Rules.

If Nasdaq determines to delist our securities from trading on its exchange and we are unable to obtain listing on another national securities exchange, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our common shares;
- the market price of our common shares;
- our ability to obtain financing for the continuation of our operations;
- the number of investors that will consider investing in our common shares;
- the number of market makers in our common shares;
- the availability of information concerning the trading prices and volume of our common shares; and
- the number of broker-dealers willing to execute trades in shares of our common shares.

Future issuance of our common shares could dilute the interests of existing shareholders

We may issue additional common shares in the future. The issuance of a substantial number of common shares could have the effect of substantially diluting the interests of our shareholders. In addition, the sale of a substantial amount of common shares in the public market, in the initial issuance, in a situation in which we acquire a company and the acquired company receives common shares as consideration and the acquired company subsequently sells its common shares, or by investors who acquired such common shares in a private placement, could have an adverse effect on the market price of our common shares.

Short sellers may be manipulative and may drive down the market price of our common shares

Short selling is the practice of selling securities that the seller does not own, but rather has borrowed or intends to borrow from a third party with the intention of buying identical securities at a later date to return to the lender. A short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. It is therefore in the short seller's interest for the price of the stock to decline, and some short sellers publish, or arrange for the publication of, opinions or characterizations regarding the relevant issuer, often involving misrepresentations of the issuer's business prospects and similar matters calculated to create negative market momentum, which may permit them to obtain profits for themselves as a result of selling the stock short.

As a public entity, we may be the subject of concerted efforts by short sellers to spread negative information in order to gain a market advantage. In addition, the publication of misinformation may also result in lawsuits, the uncertainty and expense of which could adversely impact our reputation, business, financial condition, and operating results. There are no assurances that we will not face short sellers' efforts or similar tactics in the future, and the market price of our common shares may decline as a result of their actions.

We have a significant number of restricted share units, options and warrants outstanding, and while these options and warrants are outstanding, it may be more difficult to raise additional equity capital

As of October 28, 2024, we had outstanding restricted share units, options and warrants to purchase 18,428,012 common shares, respectively. The holders of these restricted share units, options and warrants are given the opportunity to profit from a rise in the market price of our common shares. We may find it more difficult to raise additional equity capital while these options and warrants are outstanding. At any time during which these securities are likely to be exercised, we may be unable to obtain additional equity capital on more favorable terms from other sources. Additionally, the exercise of these options and warrants will cause an increase of our outstanding common shares, which could have the effect of substantially diluting the interests of our current shareholders.

Sales of a substantial number of our common shares in the public market by our existing shareholders could cause our share price to fall

Sales of a substantial number of our common shares in the public market, or the perception that these sales might occur, could depress the market price of our common shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common shares. As of October 28, 2024, we have 18,428,012 shares issuable upon exercise of restricted share units, options and warrants. Sales of shares by these shareholders could have a material adverse effect on the trading price of our common shares. We intend to register the offering, issuance, and sale of all common shares that we may issue under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements.

We are an Emerging Growth Company, which may reduce the amount of information available to investors

The Jumpstart Our Business Start-ups Act (the "JOBS Act"), and our status as a foreign private issuer will allow us to postpone the date by which we must comply with some of the laws and regulations intended to protect investors and to reduce the amount of information we provide in our reports filed with the SEC, which could undermine investor confidence in our company and adversely affect the market price of our Common shares.

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we intend to take advantage of certain exemptions from various requirements that are applicable to public companies that are not emerging growth companies including:

- the provisions of the Sarbanes-Oxley Act requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting;

- any rules that may be adopted by the Public Company Accounting Oversight Board requiring mandatory audit firm rotation or a supplement to the auditor's report on the financial statements.

We intend to take advantage of these exemptions until we are no longer an "emerging growth company." We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year of the fifth anniversary of our initial public offering in the United States, (b) in which we have total annual gross revenue of at least $1.235 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Common shares that is held by non-affiliates exceeds $700 million as of the prior June 30; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We cannot predict if investors will find our common shares or listed warrants ("Warrants") less attractive because we may rely on these exemptions. If some investors find our common shares or Warrants less attractive as a result, there may be a less active trading market for our common shares or Warrants, and our common share or Warrant price may be more volatile and may decline.

We have never paid cash dividends on our capital stock and we do not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in our common shares will likely depend on whether the price of our Common shares increases, which may not occur

We have not paid cash dividends on any capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. Consequently, in the foreseeable future, you will likely only experience a gain from your investment in our common shares if the price of our common shares increases beyond the price in which you originally acquired the common shares.

In the event a market develops for our common shares or Warrants, the market price of our common shares or Warrants may be volatile

In the event a market develops for our common shares or Warrants, the market price of our common shares or Warrants may be highly volatile. Some of the factors that may materially affect the market price of our common shares or Warrants are beyond our control, such as changes in financial estimates by industry and securities analysts, conditions or trends in the industry in which we operate or sales of our common shares or Warrants. These factors may materially adversely affect the market price of our common shares or Warrants, regardless of our performance. In addition, the public stock markets have experienced extreme price and trading volume volatility. This volatility has significantly affected the market prices of securities of many companies for reasons frequently unrelated to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our Common shares.

Our executive officers, directors and principal shareholders will maintain the ability to exert significant control over matters submitted to our shareholders for approval

Our executive officers, directors and principal shareholders who owned more than 5% of our outstanding common shares will, in the aggregate, beneficially own shares representing approximately 21.16% of our share capital. As a result, if these shareholders were to act together, they would be able to control all matters submitted to our shareholders for approval, as well as our management and affairs. For example, these persons, if they act together, would control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in management of our company that our public shareholders disagree with.

If we are or become classified as a passive foreign investment company, our U.S. shareholders may suffer adverse tax consequences as a result

Generally, for any taxable year, if at least 75% of our gross income is passive income, or at least 50% of the value of our assets is attributable to assets that produce passive income or are held for the production of passive income, including cash, we would be characterized as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes. For purposes of these tests, passive income includes dividends, interest gains from commodities and securities transactions, the excess of gains over losses from the disposition of assets which produce passive income (including amounts derived by reason of the temporary investment of funds raised in offerings of our shares) and rents and royalties other than rents and royalties which are received from unrelated parties in connection with the active conduct of a trade or business. If we are characterized as a PFIC, our U.S. shareholders may suffer adverse tax consequences, including having gains realized on the sale of our common shares treated as ordinary income, rather than capital gains, the loss of the preferential rate applicable to dividends received on our common shares by individuals who are U.S. holders, and having interest charges apply to distributions by us and gains from the sales of our shares.

Our status as a PFIC will depend on the nature and composition of our income and the nature, composition and value of our assets. Asset value is based on which the fair market value of each asset, including goodwill and going concern value (which may be determined by reference to the market value of our common shares, which may be volatile). Our status will also depend, in part, on when and how we utilize the cash proceeds from any securities offerings our business. Based upon the value of our assets, including any goodwill, and the nature and composition of our income and assets, we believe that we will be classified as a PFIC for the taxable year ending July 31, 2024, and possibly for succeeding years. However, even if we are classified as a PFIC for the year ending July 31, 2024, under an exception to the PFIC classification rules, we may be able to avoid such classification altogether if we can meet certain conditions set forth in the exception. Because the determination of whether we are a PFIC for any taxable year is a factual determination made annually after the end of each taxable year, there can be no assurance as to our status as a PFIC in any taxable year.

The tax consequences that would apply if we are classified as a PFIC would also be different from those described above if a U.S. shareholder were able to make a valid qualified electing fund ("QEF") election. If we are classified as a PFIC, then we expect to provide U.S. shareholders with the information necessary for a U.S. shareholder to make a QEF election but there is no assurance that we will do so.

If estimates of revenue, expenses, or capital or liquidity requirements change or are inaccurate, or if cash generated from operations is insufficient to satisfy liquidity requirements, the Company may arrange additional financings

BriaCell expects that its current cash and cash equivalent reserves will be sufficient to meet its anticipated needs for working capital and capital expenditures for the near future. In the future, the Company may also arrange financings to give it the financial flexibility to pursue attractive acquisition or investment opportunities that may arise. The Company may pursue additional financing through various means, including equity investments, issuances of debt, joint venture projects, licensing arrangements or through other means. The Company cannot be certain that it will be able to obtain additional financing on commercially reasonable terms or at all. The Company's ability to obtain additional financing may be impaired by such factors as the status of capital markets, both generally and specifically in the pharmaceutical and medical device industries, and by the fact that it is a new enterprise without a proven operating history. If the amount of capital raised from additional financing activities, together with revenues from operations (if any), is not sufficient to satisfy the Company's capital needs, it may not be able to develop or advance its products, execute its business and growth plans, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer or partner requirements. If any of these events occur, the Company's business, financial condition, and results of operations could be adversely affected. Any future equity financings undertaken are likely to be dilutive to existing shareholders. Finally, the terms of securities issued in future capital transactions may include preferences that are more favorable to new investors.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our shares, our share price and trading volume could decline

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding our shares, or provide more favorable relative recommendations about our competitors, the market value of our securities would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common shares and Warrants and our trading volume to decline.

Certain Canadian legislation contains provisions that may have the effect of delaying or preventing a change in control

Canadian legislation could discourage potential acquisition proposals, delay or prevent a change in control and limit the price that certain investors may be willing to pay for our subordinate voting shares. For instance, a non-Canadian must file an application for review with the Minister responsible for the Investment Canada Act and obtain approval of the Minister prior to acquiring control of a "Canadian business" within the meaning of the Investment Canada Act, where prescribed financial thresholds are exceeded. Furthermore, limitations on the ability to acquire and hold our subordinate voting shares and multiple voting shares may be imposed by the Competition Act (Canada). This legislation permits the Commissioner of Competition to review any acquisition or establishment, directly or indirectly, including through the acquisition of shares, of control over or of a significant interest in us. Otherwise, there are no limitations either under the laws of Canada or British Columbia, or in our articles on the rights of non-Canadians to hold or vote our subordinate voting shares and multiple voting shares. Any of these provisions may discourage a potential acquirer from proposing or completing a transaction that may have otherwise presented a premium to our shareholders.

Because we are a corporation incorporated in British Columbia and some of our directors and officers are resident in Canada or other countries, it may be difficult for investors in the United States to enforce civil liabilities against us based solely upon the federal securities laws of the United States. Similarly, it may be difficult for Canadian investors to enforce civil liabilities against our directors and officers residing outside of Canada

We are a corporation incorporated under the laws of British Columbia with our registered office in West Vancouver. Some of our directors and officers and the auditors or other experts named herein are residents of Canada and all or a substantial portion of our assets and those of such persons are located outside the United States. Consequently, it may be difficult for U.S. investors to effect service of process within the United States upon us or our directors or officers or such auditors who are not residents of the United States, or to realize in the United States upon judgments of courts of the United States predicated upon civil liabilities under the Securities Act. Investors should not assume that Canadian courts: (1) would enforce judgments of U.S. courts obtained in actions against us or such persons predicated upon the civil liability provisions of the U.S. federal securities laws or the securities or blue sky laws of any state within the United States, or (2) would enforce, in original actions, liabilities against us or such persons predicated upon the U.S. federal securities laws or any such state securities or blue sky laws.

Similarly, some of our directors and officers are residents of countries other than Canada and all or a substantial portion of the assets of such persons are located outside Canada. As a result, it may be difficult for Canadian investors to initiate a lawsuit within Canada against these non-Canadian residents. In addition, it may not be possible for Canadian investors to collect from these non-Canadian residents judgments obtained in courts in Canada predicated on the civil liability provisions of securities legislation of certain of the provinces and territories of Canada. It may also be difficult for Canadian investors to succeed in a lawsuit in the United States, based solely on violations of Canadian securities laws.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Cybersecurity Risk Management and Strategy

The Company depends on the proper functioning, availability and security of its information systems, including financial, data processing, communications and operating systems. Several information systems are software applications provided by third parties. Although risks from cybersecurity threats have to date not materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations or financial condition, like other companies in our industry, we could, from time to time, experience threats and security incidents related to our and our third-party vendors' information systems, including attempts to gain unauthorized access to our confidential data, and other electronic security breaches. Such cybersecurity attacks can range from individual attempts to gain unauthorized access to our information technology systems to more sophisticated security threats. While we employ a number of measures to prevent, detect and mitigate these threats, there is no guarantee such efforts will be successful in preventing a cybersecurity attack. A cybersecurity attack could compromise the confidential information of our employees, tenants and vendors. A successful cybersecurity attack could disrupt and otherwise adversely affect our business operations.

Assessment, identification and management of cybersecurity related risks are integrated into our overall risk management process. To the extent our processes identify a heightened cybersecurity related risk, risk owners are assigned to develop risk mitigation plans, which are then tracked to completion.

Cybersecurity Governance

Our Board of Directors considers cybersecurity risk as part of its risk oversight function and has delegated oversight of cybersecurity risk strategy and governance and of other information technology risks to the Audit Committee of the Board of Directors (the "Audit Committee"). The Audit Committee reports to the full Board of Directors regarding its activities, including those related to cybersecurity. Senior management, including the Company's Chief Executive Officer and Chief Financial Officer are responsible for assessing and managing cybersecurity risk, and providing briefings regarding the assessment and management of such risk to the Audit Committee, which then reports, as necessary, to the Board of Directors. Although members of our senior management do not have direct cybersecurity expertise obtained through certifications, their experience managing the Company, which includes consulting and coordinating as necessary with a third party information technology expert referred to below, enables them to effectively assess and manage material risks from cybersecurity threats.

The Company retained an information technology expert third party company to assist in managing relevant risks. In particular, the Company outsources its information technology function and monitoring to a third party provider whereby it benefits from a professionally managed network monitoring, management, maintenance, detection and response system and a 24/7 security operations center with both onsite and remote support services. Any cybersecurity incident would be reported to the Company promptly by our third party consultant and material and potentially material incidents would be assessed by management and the Audit Committee for remediation and future prevention and detection.

The Company, at least annually, updates its policies or procedures that could help mitigate cybersecurity risks. Notwithstanding the extensive approach we take to cybersecurity, we may not be successful in preventing or mitigating a cybersecurity incident that could have a material adverse effect on us. The Company has incorporated cybersecurity coverage in its insurance policies; however, there is no assurance that the insurance the Company maintains will cover all cybersecurity breaches or that policy limits will be sufficient to cover all related losses.

ITEM 2. PROPERTIES

As of August 2024, the Company commenced a month-to-month lease arrangement for office and lab space in Philadelphia, Pennsylvania, in the amount of approximately $38,110 per month. The Company also maintains office space in West Vancouver, British Columbia Canada.

ITEM 3. LEGAL PROCEEDINGS

We may be involved from time to time in ordinary litigation, negotiation, and settlement matters that will not have a material effect on our operations or finances.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market information

Our common shares and Warrants to purchase common shares trade on The Nasdaq Capital Market under the symbols "BCTX" and "BCTXW", respectively, since February 24, 2021 and on the Toronto Stock Exchange ("TSX") under the symbol "BCT" since December 31, 2021, and prior to that, on the TSX Venture Exchange from December 3, 2014.

Number of Shareholders

As of October 28, 2024, we have approximately 47 shareholders of record of our common shares.

Dividend Policy

Historically, we have not paid any cash dividends to the holders of shares of our common shares and we do not expect to pay any such dividends in the foreseeable future as we expect to retain our future earnings for use in the operation and expansion of our business.

Issuer Purchases of Equity Securities

None.

ITEM 6.

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion and other parts of this Annual Report contain forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "*Risk Factors*" and elsewhere in this Annual Report.

The preparation of our consolidated financial statements in conformity with these accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent liabilities at the financial statement date and reported amounts of revenue and expenses during the reporting period. On an on-going basis, we review our estimates and assumptions. The estimates were based on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results are likely to differ from those estimates or other forward-looking statements under different assumptions or conditions, but we do not believe such differences will materially affect our financial position or results of operations. Our actual results may differ materially as a result of many factors, including those set forth under the headings entitled "*Special Note Regarding Forward-Looking Statements*" and "*Risk Factors*".

Overview

BriaCell is a clinical-stage biotechnology company that is developing novel immunotherapies to transform cancer care. Immunotherapies have come to the forefront in the fight against cancer as they harness the body's own immune system to recognize and destroy cancer cells. The Company is currently advancing its Bria-IMT™ targeted immunotherapy in combination with an immune check point inhibitor (Retifanlimab) in a pivotal Phase 3 study in metastatic breast cancer. Bria-IMT™ is currently under Fast Track Designation by the U.S. Food and Drug Administration(the "FDA") intended to accelerate the review process of novel treatments that address unmet medical needs. Positive completion of the pivotal study, following review by FDA, could lead to full approval of the Bria-IMT™ immune checkpoint inhibitor combination in metastatic breast cancer. BriaCell reported benchmark-beating patient survival and clinical benefit in metastatic breast cancer with median overall survival of 13.4 months in BriaCell's metastatic breast cancer patients vs. 6.7-9.8 months for similar patients reported in the literature in its Phase 2 study of Bria-IMT™ combination study with retifanlimab at the 2023 San Antonio Breast Cancer Symposium. A completed Bria-IMT™ Phase 1 combination study with retifanlimab (an anti-PD1 antibody manufactured by Incyte) confirmed tolerability and early-stage efficacy. BriaCell is also developing personalized off-the-shelf immunotherapies, Bria-OTS™ and Bria-OTS+™, which provides a platform technology to develop personalized off-the-shelf immunotherapies for numerous types of cancer, and a soluble CD80 protein therapeutic which acts both as a stimulator of the immune system as well as an immune checkpoint inhibitor.

Critical Accounting Policies and Estimates

1. Critical Estimates and Judgements

The preparation of these consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The financial statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the financial statements, and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised and also in future periods when the revision affects both current and future periods.

The critical judgments and significant estimates in applying accounting policies that have the most significant effect on the amounts recognized in the consolidated financial statements are:

Going Concern

Preparation of the consolidated financial statement on a going concern basis, which contemplates the realization of assets and payments of liabilities in the ordinary course of business. Should the Company be unable to continue as a going concern, it may be unable to realize the carrying value of its assets, including its intangible assets and to meet its liabilities as they become due.

Warrants and options

The Company uses the Black-Scholes option-pricing model to estimate the fair value of options at the grant date, and the warrant liability at the grant date and each reporting period date. The key assumptions used in the model are the expected future volatility in the price of the Company's shares and the expected life of the warrants.

Income Taxes

The Company accounts for income taxes in accordance with Accounting Standard Codification 740, Income Taxes ("FASB ASC 740"), on a tax jurisdictional basis. The Company files income tax returns in the United States.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the tax bases of assets and liabilities and the consolidated financial statements reported amounts using enacted tax rates and laws in effect in the year in which the differences are expected to reverse. A valuation allowance is provided against deferred tax assets when it is determined to be more likely than not that the deferred tax asset will not be realized.

Provision for Income Taxes. Management accounts for income taxes by estimating future tax effects of temporary differences between the tax and book basis of assets and liabilities considering the provisions of enacted tax laws. The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, management is required to make many subjective assumptions and judgments regarding the Corporation's income tax exposures, including judgments in determining the amount and timing of recognition of the resulting deferred tax assets and liabilities, including projections of future taxable income. Interpretations of and guidance surrounding income tax laws and regulations change over time. As such, changes in management's subjective assumptions and judgments can materially affect amounts recognized in the Consolidated balance sheet and Consolidated Statements of Operations and Comprehensive Loss

Intangible assets

Intangible assets are tested for impairment annually or more frequently if there is an indication of impairment. The carrying value of intangibles with definite lives is reviewed each reporting period to determine whether there is any indication of impairment. If there are indications of impairment, the impairment analysis is completed and if the carrying amount of an asset exceeds its recoverable amount, the asset is impaired and impairment loss is recognized.

Prepaid expenses

The Company has prepaid certain expenses in respect of its pivotal phase III trial and estimates the period over which such expenses will be incurred. As of July 31, 2024, the Company revised its estimate of the time to completion in respect of this trial. Amounts estimated to be expenses in more than 12 months have been classified to long-term prepaid expenses.

The useful life of property and equipment

Property and equipment are depreciated over their useful lives. Useful lives are based on management's estimates of the period that the assets will be used which are periodically reviewed for continued appropriateness. Changes to estimates can result in significant variations in the amounts charged to the consolidated statement of operations and comprehensive loss in specific periods.

Investment equity method

Investments in entities over which the Company does not have a controlling financial interest but has significant influence are accounted for using the equity method, with the Company's share of losses reported in the loss from equity method investments on the statements of operation and comprehensive loss. The Company has a 51.2% interest in BC Therapeutics. Management evaluates whether it has control over the investee in accordance with the guidance of ASC 810, which requires judgment to assess factors such as power over significant activities of the investee, exposure to variable returns, and the ability to affect those returns. Based on this evaluation, management determines whether control or significant influence is present for accounting purposes.

2. New Accounting Policies Adopted

No new accounting policies were adopted during the year ended July 31, 2024.

Results of Operations

Comparison of the year ended July 31, 2024, compared to the year ended July 31, 2023

Research Costs

Research costs are comprised primarily of (i) salaries and wages to Company employees at our laboratory; and (ii) clinical trials and investigational drug costs, which include the testing and manufacture of our investigational drugs and costs of our clinical trials.

The following is a breakdown of our research and development costs by project:

	Year ended July 31,	
	2024	2023
Clinical trials	$ 15,833,879	$ 7,843,760
Pre-clinical projects	7,727,058	3,787,673
Chemical, Manufacturing and Control Costs ("CMC Costs")	1,685,223	1,801,287
Other	1,931,646	1,903,918
	$ 27,177,807	$ 15,336,638

Our clinical trial expenses include our immunotherapy program, Bria-IMT™, a 46-subject Phase 1/2a clinical trial. Clinical trial expenses increased in 2024 as we recruited more patients into the Bria-IMT™ trial and began setting up the Bria-OTS™ trial. Clinical trial expenses increased in 2024 as patients stayed in the trial for a longer period of time (i.e. a longer than expected overall survival). Additionally, our costs increased significantly compared with the same period in 2023 for much higher set up costs for the pivotal Phase 3 study of Bria-IMT™ combination regimen with Retifanlimab in advanced breast cancer, and additional expenses in preparation for the upcoming clinical studies of Bria-OTS™.

Our clinical trial expenses are broken down as follows:

	Year ended July 31,	
	2024	2023
Bria-IMT™ Pivotal Phase 3 study	$ 10,518,593	$ 2,801,978
Bria-IMT™ Phase 1/2a	3,846,033	4,577,457
Indirect research and development expenses allocated to trials	1,469,253	464,325
	$ 15,833,879	$ 7,843,760

During the year ended July 31, 2024 we pivoted from our Bria-IMT™ Phase 1/2a study to the Bria-IMT™ Pivotal Phase 3 Study.

Pre-clinical projects include expenses incurred in our off-the-shelf personalized immunotherapies, including Bria-OTS+™, and Bria-PROS™. Our pre-clinical costs have increased in 2024 as we hired more staff to accelerate our existing pre-clinical program and added an additional pre-clinical program (sCD80). Towards the end of 2024 the financial year end, we have slowed these programs in order to direct more attention and resources to our clinical trials.

CMC costs include the manufacturing of Bria-IMT™ and Bria-OTS™ and all quality control and quality assurance testing on the investigational product. CMC costs decreased in 2024; this reduction can be attributed to efficiencies gained in the manufacturing process and a streamlined approach to quality control.

Other costs are ancillary expenses we incur such as costs to maintain our patents, investigation of early-stage projects, scientific advisory board expenses, contracts with vendors for pre-clinical work, and administration costs associated with all our research and development expenditure. Other costs increased in 2024 as we investigated additional potential pre-clinical projects.

The following is a breakdown of our research and development costs by nature of expenses:

	Year ended July 31,	
	2024	2023
Clinical trial sites and investigational drug costs	$ 20,890,266	$ 9,611,630
Wages and salaries	4,567,307	3,878,367
Laboratory rent	420,310	194,880
Supplies	496,312	579,169
Depreciation	68,626	-
Share-based compensation	734,986	1,072,592
	$ 27,177,807	$ 15,336,638

For the year ended July 31, 2024, research costs totaled $27,177,807, compared to $15,336,638 for the same period in 2023. The increase primarily resulted from the expansion of the Company's Bria-IMT™ trial and higher clinical trials and investigational drug costs, which rose from $9,611,630 in 2023 to $20,890,266 in 2024. Wages and salaries increased from $3,878,367 to $4,567,307, reflecting the hiring of additional employees. Additionally, non-cash share-based compensation expenses decreased from $1,072,592 in 2023 to $734,986 in 2024, offsetting some of the overall increase in research and development expenses.

General and Administrative Expenses

For the year ended July 31, 2024, general and administrative expenses amounted to $6,152,269 as compared to $7,935,626 for the year ended July 31, 2023. The decrease in general and administrative expenses primarily stems from lower insurance premiums, professional fees and share-based compensation expenses. The Company has reduced general and administrative expenses in order to devote more resources to its clinical program.

Financial income (expenses), net

For the year ended July 31, 2024, financial income, net amounted to $262,566, compared to $850,340 for the year ended July 31, 2023. Financial income for 2024 primarily consists of interest income of $288,018, offset by a foreign exchange loss of $25,450. In comparison, for the year ended July 31, 2023, interest income was $891,213, while foreign exchange losses totaled $40,873. The decrease in financial income from 2023 to 2024 reflects lower interest income due to reduced cash and cash equivalents available for investment in interest-bearing funds.

Loss for the period

The Company reported a loss for the year ended July 31, 2024, of $4,791,466, compared to $20,302,394 for the year ended July 31, 2023. The loss in 2024 primarily stems from increased operational spending, particularly in research and development. However, the decrease in the fair value of the warrant liability substantially offset the increase in research and development expenses, leading to a significantly lower reported loss for the year. In contrast, the larger loss in 2023 is attributed to lower operational costs but a smaller decrease in the warrant liability, which did not offset expenses to the same extent as in 2024. This highlights the significant role the warrant liability valuation plays in influencing the Company’s overall financial performance.

Liquidity and Capital Resources

As of July 31, 2024, the Company has a negative working capital of ($3,807,303) (July 31, 2023- $25,147,050) and an accumulated deficit of $85,443,697 (July 31, 2023 - $80,652,231).

As of July 31, 2024, the Company's capital resources consist primarily of cash and cash equivalents, comprised mostly of cash on deposit with banks, investments in money market funds, investments in U.S. government securities, U.S. government agency securities, and investment grade corporate debt securities. Our investment policy and strategy are focused on preservation of capital and supporting our liquidity requirements.

Historically, the Company has financed its operation through private and public placement of equity securities, as well as debt financing. The Company's ability to fund its longer-term cash requirements is subject to multiple risks, many of which are beyond its control. The Company intends to raise additional capital, either through debt or equity financings in order to achieve its business plan objectives. Management believes that it can be successful in obtaining additional capital; however, there can be no assurance that the Company will be able to do so. There is no assurance that any funds raised will be sufficient to enable the Company to attain profitable operations or continue as a going concern. To the extent that the Company is unsuccessful, the Company may need to curtail or cease its operations and implement a plan to extend payables or reduce overhead until sufficient additional capital is raised to support further operations. There can be no assurance that such a plan will be successful. To this end, for several months during calendar year 2024, certain directors and officers agreed to defer payment of their directors' fees/compensation until we completed a financing, after which, these fees were paid in full. Further, certain officers have indicated their willingness to receive a portion of their compensation in shares of the Company, subject to applicable Nasdaq rules. In addition, we continue to reduce expenditure on certain non-core activities whilst maintaining our focus on our Phase 3 Bria-IMT™ pivotal study in advanced metastatic breast cancer.

During the year ended July 31, 2024, the Company's overall position of cash and cash equivalents decreased by $20,389,003 from the year ended July 31, 2023 (including effects of foreign exchange). This decrease in cash can be attributed to the following:

The Company's net cash used in operating activities during the year ended July 31, 2024, was $24,126,128 as compared to $23,744,860 for the year ended July 31, 2023. Although the operating loss was higher during the period ended July 31, 2024, this was offset by an increase in accounts payable, such that the cash flows from operating activities during both periods were similar.

Cash generated from financing activities for the year ended July 31, 2024, was $4,418,926, as compared to $3,954,300 for the year ended July 31, 2023. In both periods, this relates to proceeds for the issuance of shares.

Off-balance Sheet Arrangements

None.

Tabular Disclosure of Contractual Obligations

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this Item 7A.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The report of independent registered public accounting firm with PCAOB ID: 1930 and financial information required by this Item is attached hereto at the end of this report beginning on page F-1 and is hereby incorporated by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal accounting and financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer and principal accounting and financial officer have concluded that as of July 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the U.S. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of July 31, 2024, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control-Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on this assessment, our management concluded that, as of July 31, 2024, our internal control over financial reporting was effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There has been no material changes in our internal control over financial reporting during the quarter ended July 31, 2024. No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the quarter ended July 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting, except for our remediation efforts described above.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Executive Officers, Directors and Key Employees

The following table sets forth the name, age and position of each of our executive officers, key employees and directors as of October 28, 2024. All directors hold office until the next annual meeting of shareholders and the election and qualification of their successors. Officers serve at the discretion of the board.

Name	Age	Position
William V. Williams, MD, FRCP	69	President, Chief Executive Officer, and Director
Gadi Levin, CA, MBA	51	Chief Financial Officer and Corporate Secretary
Giuseppe Del Priore, MD, MPH	62	Chief Medical Officer
Miguel A. Lopez-Lago, PhD	55	Chief Scientific Officer
Jamieson Bondarenko, CFA, CMT	41	Chairman of the Board of Directors
Vaughn C. Embro-Pantalony, MBA, FCPA, FCMA, CDIR, ACC	68	Director
Marc Lustig, MSC, MBA	52	Director
Martin E. Schmieg	62	Director
Rebecca Taub, MD	72	Director
Jane A. Gross, PhD	67	Director

Biographies

William V. Williams, MD, President, Chief Executive Officer and Director, is a seasoned biopharmaceutical executive with over 35 years of industry and academic expertise, including significant clinical management in multinational pharmaceutical companies. Dr. Williams has served as President, Chief Executive Officer and Director of the Company since November 1, 2016. Dr. Williams served as Vice President of Exploratory Development at Incyte Corporation from March 2005 through November 2016. There he facilitated entry of over 20 compounds into the clinic, including ruxolitinib (Jakafi), and baricitinib (Olumiant), and facilitated their development through post-approval. Dr. Williams held several positions at GlaxoSmithKline Pharmaceuticals, including Head of Experimental Medicine and Vice President of Clinical Pharmacology and Experimental Medicine from December 2000 through March 2002; Director and Head of Clinical Pharmacology, Oncology, Musculoskeletal and Inflammation from March 2002 through December 2004 and Director and Head of Clinical Pharmacology, Musculoskeletal, Inflammation, Gastrointestinal and Urology from December 2004 through March 2005. He has also served as Assistant Professor of Medicine and the Director of Rheumatology Research at the University of Pennsylvania from July 1991 through January 1998. Dr. Williams earned his BSc in Chemistry and Biotechnology from Massachusetts Institute of Technology and Medical Doctorate from Tufts University School of Medicine. We believe that Dr. Williams is qualified to serve as a member of our Board because of his experience as our President and Chief Executive Officer, as well as his depth of academic and industry experience.

Gadi Levin, CA, MBA, Chief Financial Officer and Secretary, was appointed Chief Financial Officer and Secretary of the Company on February 1, 2016. Mr. Levin has also served as Chief Financial Officer and Director of Vaxil Bio Ltd since March 1, 2016, and as the Finance Director of Eco (Atlantic) Oil & Gas Ltd. since December 1, 2016. Mr. Levin has over 20 years of experience working with public U.S., Canadian and multi-jurisdictional public companies. Previously, Mr. Levin served as Chief Financial Officer of DarioHeath Corp from November 2013 through January 2015. Mr. Levin also served as the Vice President of Finance and Chief Financial Officer for two Israeli investment firms specializing in private equity, hedge funds and real estate. Mr. Levin began his CPA career at the accounting firm Arthur Andersen, where he worked for nine years, specializing in U.S. listed companies involved in initial public offerings. Mr. Levin has a Bachelor of Commerce degree in Accounting and Information Systems from the University of Cape Town, South Africa, and a post graduate diploma in Accounting from the University of South Africa. He received his Chartered Accountant designation in South Africa and has an MBA from Bar Ilan University in Israel.

Giuseppe Del Priore, MD, MPH, Chief Medical Officer, was appointed Chief Medical Officer on February 16, 2022. Dr. Del Priore is a seasoned healthcare executive with over 25 years of experience in research, drug development, and clinical trial management. Dr. Del Priore's prior work experience includes serving as a biotechnology company Chief Medical Officer, a National Director at the Cancer Treatment Centers of America, and faculty at Indiana University School of Medicine, Weill Cornell Medicine, and New York University School of Medicine. Dr. Del Priore completed his MPH degree in Biostatistics and Epidemiology at the University of Illinois Chicago School of Public Health, his medical degree with Distinction at The State University of New York, and his BA, magna cum laude, in Philosophy, at The City University of New York, with additional training at Memorial Sloan Kettering Cancer Center, The University of Chicago, Northwestern University, and the University of Rochester. He has authored numerous publications, was named on several patents, and was listed as the "Best Doctors" by the U.S. News & World Report. He regularly appears in various media outlets as a Key Opinion Leader in oncology. We believe that Dr. Del Priore is qualified to serve as Chief Medical Officer because of his medical and clinical trial experience.

Miguel A. Lopez-Lago, PhD, Chief Scientific Officer, was appointed Chief Scientific Officer on May 26, 2022, a promotion from his prior title of Senior Director, Research and Development. Since 2000, Dr. Lopez-Lago has been working as a cancer scientist at Memorial Sloan Kettering Cancer Center, New York. Specifically, he has investigated various aspects of tumor biology, including the development of targeted therapies for mesothelioma and the characterization of the biological mechanisms underlying cancer metastasis. More recently, Dr. Lopez-Lago has been interested in the study of the tumor immune-microenvironment and in the development of immunotherapies for thoracic cancers using chimeric antigen receptor T cell technologies. Since 2013, Dr. Lopez-Lago has been working as Senior Research Scientist at MSKCC. Dr. Lopez-Lago received his Bachelor of Science in Bio-Sciences and his doctorate in Molecular Biology from Santiago of Compostela University, Spain. We believe that Dr. Lopez-Lago is qualified to serve as Chief Scientific Officer because of his scientific training, especially in immunology and cellular therapies.

Jamieson Bondarenko, **CFA, CMT**, Chairman of the Board, was appointed as a Director of the Company on February 12, 2019 and elected as Chairman on April 24, 2019. Mr. Bondarenko provides strategic capital markets & corporate development advice to early-stage life sciences companies through his merchant capital company, JGRNT Capital Corp., a company he founded in November 2016. From December 2016 through October 2017, he served as Principal and Managing Director of the Equity Capital Markets group of Eight Capital. He also held several positions in the Capital Markets division of Dundee Securities Ltd., including Managing Director from July 2016 through December 2016, Director from October 2015 through July 2016, Vice President from December 2012 through October 2015 and Associate from February 2010 through December 2012. We believe that Mr. Bondarenko is qualified to serve as a member of our Board because of his industry-specific and capital markets experience.

Vaughn C. Embro-Pantalony, MBA, FCPA, FCMA, CDIR, ACC, Director, has been a Director of the Company since his appointment on March 18, 2019. In February 2018, he joined the Board of Directors of Soricimed Biopharma Inc., a private clinical-stage biopharma company developing targeted cancer therapies, and in August 2018 he was appointed Chairman of the Board of Soricimed, where he continues to serve in this capacity. He is also a Director of Microbix Biosystems Inc., a public company and leading manufacturer of viral and bacterial antigens and reagents for the global diagnostics industry. He originally joined the Microbix Board in February 2007, and he also served as its President and Chief Executive Officer from November 2012 to July 2017. He is President of Stratpath Management Inc., consulting on strategy and governance to the life sciences sector. He has held other executive positions in life sciences with responsibility for finance, business development, strategic planning and information technology, including Vice President, Finance, and Chief Financial Officer of Novopharm Limited from May 2003 through April 2006; Vice President, Information Technology, and Chief Information Officer of Bayer Inc. from July 1999 through April 2003; Vice President, Finance and Administration of Bayer Healthcare from October 1996 through June 1999; and Director, Finance and Administration and Chief Financial Officer of Zeneca Pharma Inc. from March 1995 through August 1996. He received his bachelor's degree from Wilfrid Laurier University and his master of business administration degree from University of Windsor. He is a Fellow Chartered Professional Accountant and a Chartered Director (C. Dir.) and is Audit Committee Certified (A.C.C.) through the Directors College, McMaster University. We believe that Mr. Embro-Pantalony is qualified to serve as a member of our Board due to his extensive experience as a pharmaceutical and life sciences executive.

Marc Lustig, Director, was appointed to the Company's Board on September 1, 2021. Mr. Lustig is a highly regarded investor, entrepreneur, and corporate finance veteran with a deep understanding of the life sciences industry, including biotechnology and pharmaceuticals, as well as the legal cannabis industry. He holds MSc and MBA degrees from McGill University. His professional experience includes working at Merck & Co., and his capital markets career includes roles in biotechnology equity research and corporate finance. Mr. Lustig was the founder and CEO of Origin House, which was sold to Cresco Labs Inc. (CSE: CL; OTCQX: CRLBF) in 2020. In addition to being a director of a number of public companies, he founded the Lustig Family Medical Cannabis Research & Care Fund of the Cedars Cancer Foundation that provides cannabis to palliative cancer patients. We believe that Mr. Lustig is qualified to serve as a member of our Board because of his industry-specific and capital markets experience.

Martin Schmieg, Director, rejoined the Company's Board on November 24, 2020. Having served as a member of BriaCell's Board from 2016 to March 2019, Mr. Schmieg is a "C" level executive with 30 years of business experience and a diversified background in the global biotech, pharmaceutical and med-tech industries. He currently serves as Co-Founder, Chief Executive and Financial Officer of Clear Intradermal Technologies, Inc. (formerly, ClearIt LLC), Chief Executive Officer of TrueBinding, Inc., Managing Partner of Soar Venture Capital Partners, LLC, and as a Venture Partner of Convergence Ventures LLC. As a hands-on leader, Mr. Schmieg's early career focused on accounting and financial management responsibilities, serving as Chief Financial Officer to privately held Cytometrics, Inc. and Advanced Bionics Corporation, and publicly traded Sirna Therapeutics, Inc. and Isolagen, Inc. We believe that Mr. Schmieg is qualified to serve as a member of our Board because of his long-term familiarity with the Company and his perspective and experience in relevant industries.

Rebecca Taub, MD, Director, has been a Director of the Company since her appointment on March 18, 2019. Dr. Taub currently serves as the President of Research and Development for Madrigal Pharmaceuticals, a clinical-stage biopharmaceutical company. She previously served as Vice President of Research and Development from July 2016 through her recent promotion to President of Research and Development on June 27, 2019. She has also served as Madrigal's Chief Medical Officer since July 2016. Dr. Taub served as the CEO and a Director of Madrigal from September 2011 through Madrigal's merger with Synta Pharmaceuticals Corp. in July 2016. Prior to joining Madrigal, Dr. Taub served as Senior Vice President, Research and Development of VIA Pharmaceuticals from 2008 to 2011 and as Vice President, Research, Metabolic Diseases at Hoffmann-LaRoche from 2004 to 2008. In those positions, Dr. Taub oversaw clinical development and drug discovery programs in cardiovascular and metabolic diseases, including the conduct of a series of Phase I and II proof of conduct clinical trials. Dr. Taub led drug discovery programs, including target identification, lead optimization and advancement of preclinical candidates into clinical development. From 2000 through 2003, Dr. Taub worked at Bristol-Myers Squibb Co. and DuPont Pharmaceutical Company, in a variety of positions, including Executive Director of CNS and metabolic diseases research. Before becoming a pharmaceutical executive, Dr. Taub was a tenured Professor of Genetics and Medicine at the University of Pennsylvania, and remains an adjunct professor. Dr. Taub is the author of more than 120 research articles. Before joining the faculty of the University of Pennsylvania, Dr. Taub served as an Assistant Professor at the Joslin Diabetes Center of Harvard Medical School, Harvard University and an associate investigator with the Howard Hughes Medical Institute. Dr. Taub received her M.D. from Yale University School of Medicine and her B.A. from Yale College. We believe that Dr. Taub is qualified to serve as a member of our Board due to her extensive experience as a pharmaceutical executive heading up major development programs in non-alcoholic steatohepatitis.

Jane Gross, Director, was appointed to the Company's Board in November 2021. Dr. Gross is a highly experienced biotech executive with over 30 years in leading research and development teams from discovery through preclinical evaluation and clinical development of therapeutics for the treatment of cancer and autoimmune and inflammatory diseases. Dr. Gross currently serves as an Independent Director for aTyr Pharmaceuticals (Nasdaq: LIFE), a biotechnology company developing novel therapeutics for respiratory diseases and multiple cancer indications. Dr. Gross's experience includes roles as Chief Scientific Officer and SVP, Research and Non-Clinical Development at Aptevo Therapeutics (Nasdaq: APVO), during which she led the discovery of novel antibody-based, bispecific protein therapeutics as immunotherapies to treat diseases like cancer. Previously, Dr. Gross served as VP, Applied Research and Non-Clinical Development at Emergent BioSolutions (NYSE: EBS), during which she successfully introduced a drug to patients from the design stage into the clinic stage. Formerly, as VP, Immunology Research at ZymoGenetics, Dr. Gross discovered and developed 30+ new product candidates, completed partnerships and out-licensing of assets, and helped position ZymoGenetics for a successful acquisition by Bristol Myers Squibb (NYSE: BMY) in 2010. Dr. Gross earned her Ph.D. in Immunology from the University of California, Berkeley and her Post-Doctoral Fellowship from the University of Washington in Immunology. We believe that Dr. Gross is qualified to serve as a member of our Board due to her extensive industry experience and academic background.

Family Relationships and Other Arrangements

There are no family relationships among our directors and executive officers. There are no arrangements or understandings between or among our executive officers and directors pursuant to which any director or executive officer was or is to be selected as a director or executive officer.

Composition of our Board

Under our amended articles of incorporation, our Board consists of a minimum of three directors and up to that number which was last set by ordinary resolution of the shareholders. Our Board is currently comprised of seven directors, and under the Business Corporations Act (British Columbia) ("BCBCA"), as a reporting issuer, we must have no fewer than three directors. Under the BCBCA, a director may be removed with or without cause by a resolution passed by at least two-thirds of the votes cast by shareholders present in person or by proxy at a meeting and who are entitled to vote. The directors are appointed at the annual general meeting of shareholders and the term of office for each of the directors will expire at the time of our next annual shareholders meeting. Our amended articles of incorporation provide that, between annual general meetings of our shareholders, the directors may appoint one or more additional directors, but the number of additional directors may not at any time exceed one-third of the number of directors who held office at the expiration of the last meeting of our shareholders. Under the BCBCA, there is no minimum number of directors required to be resident Canadians as defined in the BCBCA.

Director Term Limits and Other Mechanisms of Board Renewal

Our Board has not adopted director term limits or other automatic mechanisms of Board renewal. Rather than adopting formal term limits, mandatory age-related retirement policies and other mechanisms of Board renewal, the nominating and corporate governance committee of our Board will develop a skills and competencies matrix for our Board as a whole and for individual directors. The nominating and corporate governance committee conducts a process for the assessment of our board of directors, each committee and each director regarding his or her effectiveness and contribution, and reports evaluation results to our Board on a regular basis.

Director Independence

Under the Nasdaq Rules, independent directors must comprise a majority of a listed company's board of directors. For purposes of the Nasdaq Rules, an independent director means a person other than an executive officer or employee of the company who, in the opinion of the board of directors, has no relationship with the company that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Under NI 58-101, a director is considered to be independent if he or she is independent within the meaning of Section 1.4 of National Instrument 52-110-*Audit Committees*. Section 1.4 of NI 52-110 generally provides that a director is independent if he or she has no direct or indirect relationship with the issuer which could, in the view of the issuer's board of directors, be reasonably expected to interfere with the exercise of the director's independent judgment.

Our Board has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our Board has determined that Dr. Gross, Dr. Taub, Mr. Embro-Pantalony, Mr. Schmieg, and Mr. Bondarenko, representing five of the seven members of our Board, are "independent" as that term is defined under the Nasdaq Rules. In making this determination, our Board considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our shares by each non-employee director. Dr. Williams is not independent by virtue of being the Company's Chief Executive Officer. Mr. Lustig is not independent by virtue of being a significant securityholder of the Company.

Certain members of our Board are also members of the boards of other public companies. Our Board has not adopted a director interlock policy, but is kept informed of other public directorships held by its members.

Mandate of the Board of Directors

Our Board is responsible for supervising the management of our business and affairs, including providing guidance and strategic oversight to management. Our Board's mandate includes, among other things, the following matters:

- succession planning, including appointing, training and monitoring senior management;
- developing the corporate goals and objectives that management is responsible for meeting and reviewing the performance of our senior officers against such corporate goals and objectives;
- taking steps to satisfy itself as to the integrity of our executive officers and that our executive officers create a culture of integrity throughout the organization;
- reviewing and approving our code of conduct and reviewing and monitoring compliance with the code of conduct and our enterprise risk management processes;
- reviewing and approving management's strategic and business plans and our financial objectives, plans and actions, including significant capital allocations and expenditures; and
- reviewing and approving material transactions not in the ordinary course of business.

Meetings of Independent Directors

Our Board holds regularly-scheduled quarterly meetings as well as *ad hoc* meetings from time to time. The independent members of our Board also meet, as required, without the non-independent directors and members of management after each regularly scheduled board meeting.

A director who has a material interest in a matter before our Board or any committee on which he or she serves is required to disclose such interest as soon as the director becomes aware of it. In situations where a director has a material interest in a matter to be considered by our Board or any committee on which he or she serves, such director may be required to absent himself or herself from the meeting while discussions and voting with respect to the matter are taking place. Directors are also required to comply with the relevant provisions of the BCBCA regarding conflicts of interest.

Position Descriptions

Our Board has adopted written terms of reference for the chairman which set out his or her key responsibilities, including duties relating to determining the frequency, dates and locations of meetings and setting Board meeting agendas, chairing Board and shareholder meetings and carrying out any other or special assignments or any functions as may be requested by our Board or management, as appropriate.

Our Board has also adopted written terms of reference for each of the committee chairs which set out each of the committee chair's key responsibilities, including duties relating to determining the frequency, dates and locations of meetings and setting committee meeting agendas, chairing committee meetings, reporting to our Board and carrying out any other special assignments or any functions as may be requested by our Board.

In addition, our Board, in conjunction with our Chief Executive Officer, will develop and implement a written position description for the role of our Chief Executive Officer.

Orientation and Continuing Education

We have implemented an orientation program for new directors under which a new director meets separately with the chairman of our Board, members of the senior executive team and the secretary.

The nominating and corporate governance committee will be responsible for coordinating orientation and continuing director development programs relating to the committee's mandate. The chairman of our Board will be responsible for overseeing director continuing education designed to maintain or enhance the skills and abilities of our directors and to ensure that their knowledge and understanding of our business remains current.

Code of Conduct

Our board of directors has adopted a Code of Ethics that applies to all of our directors, officers and employees. We have made the Code of Ethics available on our website https://briacell.com/corporate/corporate-governance/. We intend to disclose future amendments to, or waivers of, our Code of Ethics, as and to the extent required by SEC regulations, at the same location on our website identified above or in public filings.

Monitoring Compliance with the Code of Conduct

Our nominating and corporate governance committee will be responsible for reviewing and evaluating the code of conduct at least annually and will recommend any necessary or appropriate changes to our Board for consideration. The nominating and corporate governance committee will assist our Board with the monitoring of compliance with the code of conduct, and will be responsible for considering any waivers therefrom (other than waivers applicable to members of the nominating and corporate governance committee, which shall be considered by the audit committee, or waivers applicable to our directors or executive officers, which shall be subject to review by our Board as a whole).

Requirement for Directors and Officers to Disclose Interest in a Contract or Transaction

In accordance with the BCBCA, each director and officer must disclose the nature and extent of any interest that he or she has in a material contract or material transaction whether made or proposed with us, if the director or officer is a party to the contract or transaction, is a director or an officer or an individual acting in a similar capacity of a party to the contract or transaction, or has a material interest in a party to the contract or transaction. Subject to certain limited exceptions under the BCBCA, no director may vote on a resolution to approve a material contract or material transaction which is subject to such disclosure requirement.

As of the date hereof, except as otherwise disclosed in this Annual Report on Form 10-K, to the knowledge of the Board or the management of the Company, there are no material interests, whether direct or indirect, of any informed person of the Company, any proposed director of the Company, or any associate or affiliate of any informed person or proposed director, in any transaction since the commencement of the Company's most recently completed financial year or in any proposed transaction which has materially affected or would materially affect the Company of any of its subsidiaries.

Benefits upon Termination of Employment

The service contracts with our directors do not provide for any benefits upon termination of employment, other than a "tail" directors and officers insurance policy.

Complaint Reporting

In order to foster a climate of openness and honesty in which any concern or complaint pertaining to a suspected violation of the law, our code of conduct or any of our policies, or any unethical or questionable act or behavior, our code of conduct will require that our employees promptly report the violation or suspected violation. In order to ensure that violations or suspected violations can be reported without fear of retaliation, harassment or an adverse employment consequence, we will adopt a whistleblowing policy which will contain procedures that are aimed to facilitate confidential, anonymous submissions of complaints by our directors, officers, employees and others.

Committees of the Board

We currently have an audit committee, a compensation committee and a nominating and corporate governance committee, with each committee having a written charter.

Audit Committee

Our Audit Committee is currently comprised of Vaughn C. Embro-Pantalony, Martin Schmieg and Jane A. Gross, and chaired by Mr. Embro-Pantalony. Our Board has determined that each of Mr. Schmieg and Mr. Embro-Pantalony is financially literate and meets the independence requirements for directors, including the heightened independence standards for members of the audit committee under Rule 10A-3 under the Exchange Act and NI 52-110. Our Board has determined that Mr. Embro-Pantalony is "financially sophisticated" within the meaning of the Nasdaq Rules, "financially literate" within the meaning of NI 52-110, and a "financial expert" as defined by Rule 10A-3 under the Exchange Act.

We have adopted an Audit Committee Charter setting forth the purpose, composition, authority and responsibility of the audit committee. The primary function of the audit committee is to assist the Board in fulfilling its financial oversight responsibilities by reviewing the financial reports and other financial information provided by the company to regulatory authorities and the Company's shareholders, the Company's systems of internal controls regarding finance and accounting and the Company auditing, accounting and financial reporting processes. Consistent with this function, the Committee will encourage continuous improvement of, and should foster adherence to, Company's policies, procedures and practices at all levels. The Committee's primary duties and responsibilities are to:

- Serve as an independent and objective party to monitor the Company's financial reporting and internal control system and review Company's financial statements;
- Review and appraise the performance of the Company's external auditors; and
- Provide an open avenue of communication among the Company's auditors, financial and senior management and the Board.

During the year ended July 31, 2024, the Audit Committee held 5 meetings in person or through conference calls. As part of its job to foster open communication, the Audit Committee meets at least annually with the external auditors.

To fulfill its responsibilities and duties, the Audit Committee:

- Reviews and updates the Audit Committee's charter annually;
- Reviews the Company's consolidated financial statements, Management Discussion & Analysis and any annual and interim earnings, press releases before the Company publicly discloses this information and any reports or other financial information (including quarterly financial statements), which are submitted to any governmental body, or to the public, including any certification, report, opinion, or review rendered by the external auditors;
- Reviews annually, the performance of the external auditors who shall be ultimately accountable to the Board and the Committee as representatives of the shareholders of the Company;
- Obtains annually, a formal written statement of external auditors setting forth all relationships between the external auditors and the Company, consistent with Independence Standards Board Standard I;
- Reviews and discusses with the external auditors any disclosed relationships or services that may impact the objectivity and independence of the external auditors;
- Takes, or recommends that the full Board takes, appropriate action to oversee the independence of the external auditors;
- Recommends to the Board the selection and, where applicable, the replacement of the external auditors nominated annually for shareholder approval;
- Reviews and approves the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditors of the Company;
- Reviews and pre-approves all audit and audit-related services and the fees and other compensation related thereto;
- In consultation with the external auditors, reviews with management the integrity of the Company's financial reporting process, both internal and external;

- Considers the external auditors' judgments about the quality and appropriateness of the Company's accounting principles as applied in its financial reporting;
- Considers and approves, if appropriate, changes to the Company's auditing and accounting principles and practices as suggested by the external auditors and management;
- Reviews significant judgments made by management in the preparation of the financial statements and the view of the external auditors as to appropriateness of such judgments;
- Following completion of the annual audit, reviews separately with management and the external auditors any significant difficulties encountered during the course of the audit, including any restrictions on the scope of work or access to required information;
- Reviews any significant disagreement among management and the external auditors in connection with the preparation of the financial statements;
- Reviews with the external auditors and management the extent to which changes and improvements in financial or accounting practices have been implemented;
- Reviews any complaints or concerns about any questionable accounting, internal accounting controls or auditing matters;
- Reviews certification process; and
- Reviews any related-party transactions.

Principal Accountant's Fees

External Audit Service Fees

The following table sets forth the aggregate fees paid to the Company's external auditors, Chartered Professional Accountants, by the Company during the financial years ended July 31, 2024 and 2023:

	Year ended July 31, 2024	Year ended July 31, 2023
Audit Fees	$ 210,778	$ 153,000
Audit-Related Fees	-	113,000
Tax Fees	18,650	81,400
All Other Fees	14,530	-
Total:	$ 243,958	$ 347,400

Compensation Committee

Our compensation committee is comprised of Mr. Embro-Pantalony, Mr. Marc Lustig and Mr. Schmieg and is chaired by Mr. Schmieg. The Compensation Committee is appointed by the Board to assist in promoting a culture of integrity throughout the Company, to assist the Board in setting director and senior executive compensation, and to develop and submit to the Board recommendations with respect to other employee benefits as the Compensation Committee sees fit. In the performance of its duties, the Compensation Committee is guided by the following principles:

- offering competitive compensation to attract, retain and motivate highly qualified executives in order for the Company to meet its goals; and

- acting in the interests of the Company and the shareholders by being fiscally responsible.

The Board relies on the knowledge and experience of the members of the Compensation Committee to set appropriate levels of compensation for senior officers. Neither the Company nor the Compensation Committee currently has, or has had at any time since incorporation, any contractual arrangement with any executive compensation consultant who has a role in determining or recommending the amount or form of senior officer compensation.

When determining compensation payable, the Compensation Committee considers both external and internal data. External data includes general market conditions and well as information regarding compensation paid to directors, CEOs and CFOs of companies of similar size and at a similar stage of development in the industry. Internal data includes annual reviews of the performance of the directors, CEO and CFO in light of the Company's corporate objectives and considers other factors that may have impacted the Company's success in achieving its objectives. During the year ended July 31, 2024, the Compensation Committee held two meetings in person or through conference calls.

Nominating and Corporate Governance Committee

The Nominating and Corporate Governance Committee is appointed by the Board to assist in fulfilling its corporate governance responsibilities under applicable laws. The Nominating and Corporate Governance Committee is responsible for, among other things, developing the Company's approach to governance issues and establishing sound corporate governance practices that are in the interests of shareholders and that contribute to effective and efficient decision-making.

Our Nominating and Corporate Governance Committee is currently comprised of Mr. Marc Lustig and Dr. Taub and is chaired by Mr. Lustig. During the year ended July 31, 2024, the Nominating and Corporate Governance Committee held one meeting.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the BCBCA, a company may indemnify: (i) a current or former director or officer of that company; (ii) a current or former director or officer of another corporation if, at the time such individual held such office, the corporation was an affiliate of the company, or if such individual held such office at the company's request; or (iii) an individual who, at the request of the company, held, or holds, an equivalent position in another entity (an "indemnifiable person") against all costs, charges and expenses, including an amount paid to settle an action or satisfy a judgment, reasonably incurred by him or her in respect of any civil, criminal, administrative or other legal proceeding or investigative action (whether current, threatened, pending or completed) in which he or she is involved because of that person's position as an indemnifiable person, unless: (i) the individual did not act honestly and in good faith with a view to the best interests of such company or the other entity, as the case may be; or (ii) in the case of a proceeding other than a civil proceeding, the individual did not have reasonable grounds for believing that the individual's conduct was lawful. A company cannot indemnify an indemnifiable person if it is prohibited from doing so under its articles or by applicable law. A company may pay, as they are incurred in advance of the final disposition of an eligible proceeding, the expenses actually and reasonably incurred by an indemnifiable person in respect of that proceeding only if the indemnifiable person has provided an undertaking that, if it is ultimately determined that the payment of expenses was prohibited, the indemnifiable person will repay any amounts advanced. Subject to the aforementioned prohibitions on indemnification, a company must, after the final disposition of an eligible proceeding, pay the expenses actually and reasonably incurred by an indemnifiable person in respect of such eligible proceeding if such indemnifiable person has not been reimbursed for such expenses, and was wholly successful, on the merits or otherwise, in the outcome of such eligible proceeding or was substantially successful on the merits in the outcome of such eligible proceeding. On application from an indemnifiable person, a court may make any order the court considers appropriate in respect of an eligible proceeding, including the indemnification of penalties imposed or expenses incurred in any such proceedings and the enforcement of an indemnification agreement. As permitted by the BCBCA, under Article 21.1, we are required to indemnify our directors and former directors (and such individual's respective heirs and legal representatives) and we will indemnify any such person to the extent permitted by the BCBCA**.**

The BCBCA provides certain protections under Part 5 - *Management,* Division 5 - *Indemnification of Directors and Officers and Payment of Expenses,* to our current and former directors and officers, as well as other eligible parties defined in Section 159 of the BCBCA (the "Eligible Parties", each an "Eligible Party"). The Company will indemnify the Eligible Parties, to the fullest extent permitted by law and subject to certain limitations listed in Section 163 of the BCBCA, against any proceeding in which an Eligible Party or any of the heirs and personal or other legal representatives of the Eligible Party, by reason of the Eligible Party being or having been a director or officer of, or holding or having held a position equivalent to that of a director or officer of, the Company or an associated corporation (a) is or may be joined as a party, or (b) is or may be liable for or in respect of a judgment, penalty or fine in, or expenses related tom, the proceeding.

We maintain insurance policies relating to certain liabilities that our directors and officers may incur in such capacity.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table presents the compensation awarded to, earned by or paid to each of our named executive officers for the years ended July 31, 2024 and July 31, 2023.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)(1)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
William V. Williams, MD, FRCP	2023	736,555(2)	48,750		430,209	-	1,215,514
President and Chief Executive Officer	2024	734,419	-		342,651	-	1,077,070
Gadi Levin, CA, MBA	2023	285,715	18,750	-	86,970	-	391,435
Chief Financial Officer and Corporate Secretary	2024	443,000	-		77,730		520,730
Giuseppe Del Priore, MD, MPH	2023	466,927	25,578	-	456,396	-	948,901
Chief Medical Officer	2024	540,329	-		240,516	-	780,844
Miguel A. Lopez-Lago, PhD	2023	282,247	16,650	-	69,547	-	368,444
Chief Scientific Officer	2024	357,745	-		35,863		393,608

(1) This column represents the grant date fair value of the award in accordance with stock-based compensation rules under Accounting Standards Codification Topic 718. For a more detailed discussion of the valuation model and assumptions used to calculate the fair value of each option award, refer to Note 2 of the financial statements included in this annual report.

(2) Dr. Williams has indicated his willingness to receive a portion (approximately $281,250) of his compensation in shares of the Company, subject to applicable Nasdaq rules. The Company anticipates that these shares/RSU's will be issued in November 2024

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding option and RSU awards held by each of our named executive officers that were outstanding as of July 31, 2024.

	Option Awards				Stock Awards	
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market value of shares or units of stock that have not vested ($)
William V. Williams, MD, FRCP	200,000	-	4.24	03/29/26	-	-
	22,300	-	8.47	01/13/27	-	-
	101,800	-	6.14	08/02/27	-	-
	25,000	15,000	6.03	06/20/28	15,000	-
		-	0.00	08/02/27	-	
Gadi Levin, CA, MBA	75,000	-	4.24	03/29/26	-	
	20,000	-	4.71	05/20/27	-	-
	20,300	-	6.14	08/02/27	-	-
Giuseppe Del Priore, MD, MPH	150,000	-	7.51	02/16/27	-	-
	10,000	-	6.14	08/02/27	-	-
Miguel A. Lopez-Lago, PhD	15,000	-	8.47	01/13/27	-	-
	10,000	-	6.14	08/02/27	-	-

(1) Restricted Share Units

Non-Employee Director Compensation

The following table presents the total compensation for each person who served as a non-employee member of our Board and received compensation for such service during the fiscal year ended July 31, 2024. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our Board in 2024.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Jamieson Bondarenko, CFA, CMT	204,786	-	459,321	-	664,106
Vaughn C. Embro-Pantalony, MBA, FCPA, FCMA, CDIR, ACC	84,016	-	91,864	-	175,880
Marc Lustig, MSC, MBA	66,060	-	91,864	-	157,924
Martin E. Schmieg	75,000	-	91,864	-	166,864
Rebecca Taub, MD	50,004	-	91,864	-	141,868
Jane A. Gross, PhD	54,996	-	91,864	-	146,860

Employment Agreements

Dr. Williams V. Williams

On August 31, 2021, we entered into a compensation package with Dr. Williams, our Chief Executive Officer (the "2021 Compensation Package"). Pursuant to the 2021 Compensation Package, Mr. Williams receives $550,000 annually and may earn an equity incentive bonus compensation, which may include a direct stock award of up to $125,000 based upon a performance review as of December 31, 2021 (the "Performance Review"). In addition, the 2021 Compensation Package provides for an option award to purchase up to $250,000 in common shares of the Company, in connection with the Performance Review, which vests over a four year period and provides for an aggregate cash, stock and option award of up to $950,000.

On June 21, 2022, we entered into a compensation package with Dr. Williams (the "2022 Compensation Package"). Pursuant to the 2022 Compensation Package, Mr. Williams receives $650,000 annually and an annual bonus of $150,000. In addition, the 2022 Compensation Package provides for a performance stock option award of $250,000 and a total cash, bonus and option award of up to $1,050,000. On May 1, 2023, Dr. Williams' annual salary was increased to $675,000 per annum.

Giuseppe Del Priore

On February 14, 2022, we entered into an employment agreement with Dr. Giuseppe Del Priore, our Chief Medical Officer (the "Del Priore Employment Agreement"). The Del Priore Employment Agreement provides for a full-time position, $350,000 annual salary and standard employee benefit plan participation. In addition, Mr. Del Priore was granted an option to purchase 150,000 of the Company's common shares. The Del Priore Employment Agreement provides that Mr. Del Priore is eligible for an annual bonus in either cash or options to purchase common shares of the Company based on the successful completion of certain corporate milestones selected by our Chief Executive Officer and reviewed in the sole discretion of our Board or a compensation committee. On May 1, 2023, Dr. Giuseppe Del Priore's annual salary was increased to $460,000 per annum.

Gadi Levin

On March 2, 2022, we entered into an executive employment agreement with Gadi Levin, our Chief Financial Officer (the "Levin Employment Agreement"), effective January 1, 2022. The Levin Employment Agreement provides for a part-time position (80%), $350,000 annual salary ("Base Salary") and standard employee benefit plan participation. Our Board approved a annual discretionary bonus of (i) up to 30% of Mr. Levin's yearly salary; and (ii) $100,000 in stock options, which vest over a four year period per calendar year. In addition, Mr. Levin was granted 20,000 options in accordance with the terms of the Company's stock option plan. During August 2022, Mr. Levin's Base Salary was increased to $250,000, retroactively to January 1, 2022. On May 1, 2023, Mr. Levin's Base Salary was increased to $350,000 per annum.

Miguel Lopez-Lago

On May 26, 2022, we entered into an employment agreement with Miguel Lopez-Lago, our Chief Scientific Officer (the "Lopez-Lago Employment Agreement"). The Lopez-Lago Employment Agreement provides for $210,000 annually for Mr. Lopez-Lago's duties as our Chief Scientist Officer. On May 1, 2023, Mr. Lopez-Lago's annual salary was increased to $325,000 per annum.

Equity Compensation Plan Information

The following table summarizes the total number of outstanding awards and shares available for other future issuances of options under all of our equity compensation plans as of July 31, 2024. All of the outstanding awards listed below were granted under our stock option plan.

Plan Category	Number of Shares to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights	Number of Shares Remaining Available for Future Issuance Under the Equity Compensation Plan (Excluding Shares in First Column)
Equity compensation plans approved by shareholders	12,752,637	$ 5.12	611,299
Equity compensation plans not approved by shareholders	-	-	-

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information regarding the beneficial ownership of our common shares as of October 28, 2024 by:

- each of our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each shareholder known by us to own beneficially more than 5% of our common shares.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Common shares that may be acquired by an individual or group within 60 days of October 28, 2024, pursuant to the exercise of options or warrants, vesting of common shares or conversion of preferred stock or convertible debt, are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Percentage of ownership is based on 36,183,161 common shares issued and outstanding as of October 28, 2024.

Except as indicated in footnotes to this table, we believe that the shareholders named in this table have sole voting and investment power with respect to all common shares shown to be beneficially owned by them, based on information provided to us by such shareholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o BriaCell Therapeutics Corp., Suite 300 - 235 15th Street, West Vancouver, BC V7T 2X1.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Common Shares Beneficially Owned
Directors and Named Executive Officers		
Jamieson Bondarenko, CFA, CMT[1]	769,856	4.07%
William V. Williams, MD, FRCP[2]	552,738	3.00%
Gadi Levin, CA, MBA[3]	118,110	*
Giuseppe Del Priore, MD, MPH[4]	160,000	*
Miguel A. Lopez-Lago, PhD[5]	25,000	*
Vaughn C. Embro-Pantalony, MBA, FCPA, FCMA, CDIR, ACC[6]	114,524	*
Marc Lustig, MSC, MBA	3,595,870	10.03%
Martin E. Schmieg[7]	105,574	*
Rebecca Taub, MD[8]	50,000	*
Jane A. Gross, PhD[9]	90,000	*
All current named executive officers and directors as a group (10 persons)	5,581,672	15.58%
5% or Greater Shareholders		
Marc Lustig, MSC, MBA (10)	3,595,870	10.03%
CVI Investments, Inc.[11]	2,608,695	7.28%

* Represents beneficial ownership of less than 1%.

Notes :

(1) Includes 150,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 250,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027, 150,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028 and 100,000 BriaCell Warrants to purchase common shares with an exercise price of $5.3125, expiring on February 26, 2026.
(2) Includes 200,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 22,300 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027, 101,800 shares underlying options with an exercise price of C$8.38, expiring on August 2, 2027, 40,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028 and 29,802 BriaCell Warrants to purchase common shares with an exercise price of $5.3125, expiring on February 26, 2026 and 19,200 restricted share units.
(3) Includes 75,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 20,000 shares underlying options with an exercise price of $4.71, expiring on May 20, 2027 and 20,300 shares underlying options with an exercise price of C$8.38, expiring on August 2, 2027.
(4) Includes 150,000 shares underlying options with an exercise price of $7.51, expiring on February 16, 2027 and 10,000 shares underlying options with an exercise price of C$8.38, expiring on August 2, 2027.
(5) Includes 15,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027 and 10,000 shares underlying options with an exercise price of C$8.38, expiring on August 2, 2027.
(6) Includes 25,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 50,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027 and 25,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028.
(7) Includes 25,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 50,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027 and 40,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028.
(8) Includes 10,000 shares underlying options with an exercise price of $4.24, expiring on March 29, 2026, 10,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027 and 40,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028.
(9) Includes 10,000 shares underlying options with an exercise price of C$9.92, expiring on November 1, 2025, 50,000 shares underlying options with an exercise price of $8.47, expiring on January 13, 2027 and 40,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028.
(10) Includes 100,000 shares underlying options with an exercise price of $5.74, expiring on September 1, 2026, 40,000 shares underlying options with an exercise price of $6.03, expiring on June 20, 2028 and 20,000 BriaCell Warrants to purchase common shares with an exercise price of $5.3125, expiring on February 26, 2026.
(11) Based solely on a Schedule 13G filed with the SEC on September 16, 2024. The Schedule 13G was filed by CVI Investments, Inc. and Heights Capital Management, Inc. According to the Schedule 13G, as of September 16, 2024, CVI Investments, Inc. and Heights Capital Management, Inc. have shared voting power and shared dispositive power with regard to 2,608,695 common shares, representing approximately 7.28% of the outstanding common shares.

Section 16(A) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our officers and directors, and persons who own more than 10% of a registered class of our equity securities, to file reports of ownership and changes in ownership with the SEC. Officers, directors and greater than 10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based on a review of the copies of such forms received, we believe that during the fiscal year ending July 31, 2024, all filing requirements applicable to our officers, directors and greater than 10% beneficial owners were complied with, except for one late Form 4 filing for Marc Lustig with respect to his purchase of common shares and warrants in our May 2024 offering.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Other than as set forth below, there have been no transactions since August 1, 2023 to which we have been a party, including transactions in which the amount involved in the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described elsewhere in this Annual Report on Form 10-K. Other than as set forth below, we are not a party to a current related party transaction, and no transaction is currently proposed, in which the amount of the transaction exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years and in which a related person had or will have a direct or indirect material interest.

On May 17, 2024 we issued and sold to a director 902,935 common shares together with warrants to purchase up to 902,935 common shares at a combined purchase price of $2.215 per share and accompanying warrant. The warrants will be exercisable six months from the date of issuance at an exercise price of $2.11 per share and will expire on the five year anniversary of the initial exercise date.

Director Independence

Our board of directors undertook a review of the independence of our directors and considered whether any director has a relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors has affirmatively determined that Dr. Gross, Dr. Taub. Mr. Bondarenko, Mr. Empro-Pantalony, Mr. Lustig, and Mr. Schmieg are each an "independent director," as defined under the Nasdaq rules.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Audit Fees

The aggregate fees billed to us by MNP LLP, our independent registered public accounting firm, for the indicated services for each of the last two fiscal years were as follows:

	2024	2023
Audit fees (1)	$ 210,778	$ 153,000
Audit-related fees (2)	$ -	$ 113,000
Tax fees	$ 18,650	$ 81,400
All other fees	$ 14,530	$ -

(1) Audit fees consist of fees for professional services performed by MNP LLP for the audit and review of our quarterly financial statements.
(2) Audit related fees consist of fees for preparation and filing of the carve-out financial statements related to the proxy statement filed.

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Auditors

Consistent with SEC policies and guidelines regarding audit independence, the Audit Committee is responsible for the pre-approval of all audit and permissible non-audit services provided by our independent registered public accounting firm on a case-by-case basis. Our Audit Committee has established a policy regarding approval of all audit and permissible non-audit services provided by our principal accountants. Our Audit Committee pre-approves these services by category and service. Our Audit Committee has pre-approved all of the services provided by our independent registered public accounting firm.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Exhibit Number	Description of Exhibit
	(a)(1) ***Financial Statements*** The financial statements required by this item are submitted in a separate section beginning on page F-1 of this Annual Report on Form 10-K.
(b) Exhibits	
3.1	Articles of BriaCell Therapeutics Corp, dated July 26, 2006 (incorporated by reference to Exhibit 3.1 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
3.2	Notice of Articles, dated November 25, 2014 (incorporated by reference to Exhibit 3.2 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
3.3	Notice of Articles, dated August 22, 2019 (incorporated by reference to Exhibit 3.4 to our Registration Statement on Form F-1 filed with the SEC on June 15, 2021)
3.4	Alteration to Articles filed February 13, 2023 (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on February 15, 2023)
3.5	Notice of Articles filed August 31, 2023 (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on September 7, 2023)
3.6	Notice of Articles filed August 31, 2023 (incorporated by reference to Exhibit 3.2 to Form 8-K filed with the SEC on September 7, 2023)
4.1	Description of Securities Registered Under Section 12 of the Exchange Act (incorporated by reference to Exhibit 4.1 to our Form 10-K filed with the SEC on October 25, 2023)
4.2	Warrant Agent Agreement by and among the Company, Computershare Inc. and Computershare Trust Company, N.A., and Form of Warrant for Registered Offering (incorporated by reference to Exhibit 4.1 to our Registration Statement on Form F-1 filed with the SEC on January 23, 2020)
4.3	Form of Underwriter's Warrant (incorporated by reference to Exhibit 4.3 to our Registration Statement on Form F-1 filed with the SEC on February 18, 2021)
4.4	Form of Warrant issued May 17, 2024 (incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on May 17, 2024)
4.6	Form of Warrant issued June 7, 2021 (incorporated by reference to Exhibit 4.8 to our Registration Statement on Form F-1 filed with the SEC on June 15, 2021)
4.7	Form of Placement Agent Warrant issued June 7, 2021 (incorporated by reference to Exhibit 4.3 to Form 6-K filed with the SEC on June 4, 2021)

4.8	Form of Pre-funded Warrant issued May 17, 2024 (incorporated by reference to Exhibit 4.2 to Form 8-K filed with the SEC on May 17, 2024)
4.9	Form of Placement Agent Warrant issued May 17, 2024 (incorporated by reference to Exhibit 4.3 to Form 8-K filed with the SEC on May 17, 2024)
4.10	Form of Placement Agent Warrant issued September 12, 2024 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on September 12, 2024)
4.11	Form of Warrant issued October 2, 2024 (incorporated by reference to Exhibit 4.1 to Form 8-K filed with the SEC on October 2, 2024)
4.12	Form of Placement Agent Warrant issued October 2, 2024 (incorporated by reference to Exhibit 4.1 to our Form 8-K filed with the SEC on September 12, 2024)
10.1	Stock Option Plan, dated November 25, 2014 (incorporated by reference to Exhibit 10.1 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.2	Service Agreement with UC Davis, dated June 11, 2015 (incorporated by reference to Exhibit 10.2 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.3	Form of Registration Rights Agreement dated June 3, 2021 (incorporated by reference to Exhibit 10.3 to Form 6-K filed with the SEC on June 4, 2021)
10.5	Amendment #1 to Service Agreement with UC Davis, dated June 12, 2016 (incorporated by reference to Exhibit 10.5 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.8	Licensing Agreement between Faller & Williams Technology LLC and Sapientia Pharmaceuticals, Inc., dated March 16, 2017 (incorporated by reference to Exhibit 10.8 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.9	Master Services Agreement with KBI Biopharma, Inc., dated March 17, 2017 (incorporated by reference to Exhibit 10.9 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.10	Clinical Study Agreement with Cancer Insight, LLC, dated September 29, 2017 (incorporated by reference to Exhibit 10.11 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.11	Amendment #2 to Service Agreement with UC Davis, dated August 27, 2018 (incorporated by reference to Exhibit 10.15 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.12	Master Services Agreement, dated February 27, 2020 (incorporated by reference to Exhibit 10.16 to Form 10-K filed with the SEC on October 25, 2023)
10.13	First Supplement to Clinical Study Agreement with Cancer Insight, LLC, dated October 18, 2018 (incorporated by reference to Exhibit 10.19 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)

10.14	Amendment #1 to Services Agreement with Colorado State University, dated April 2, 2019 (incorporated by reference to Exhibit 10.20 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.15	Stem Cell Program Services Agreement with UC Davis, May 3, 2019 (incorporated by reference to Exhibit 10.21 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.16	HLA Typing Services Agreement with Histogenetics, dated October 3, 2019 (incorporated by reference to Exhibit 10.23 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.17	Procurement Agreement with Catalent Pharma Solutions, LLC, dated June 13, 2019 (incorporated by reference to Exhibit 10.24 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.18	Clinical Supply Services Agreement with Catalent Pharma Solutions, LLC, dated June 13, 2019 (incorporated by reference to Exhibit 10.25 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.19	Quality Agreement with Catalent Pharma Solutions, LLC, dated June 25, 2019 (incorporated by reference to Exhibit 10.26 to our Registration Statement on Form F-1 filed with the SEC on October 22, 2019)
10.20	Cooperative Research and Development Agreement, dated October 28, 2020 (incorporated by reference to Exhibit 10.44 to our Registration Statement on Form F-1 filed with the SEC on June 15, 2021)
10.21	Form of Securities Purchase Agreement dated June 3, 2021 (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on June 4, 2021)
10.22	Form of Placement Agency Agreement dated June 3, 2021 (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on June 4, 2021)
10.23+	Compensation Agreement with Dr. William V. Williams, dated August 31, 2021 (incorporated by reference to Exhibit 10.22 to Form 10-K filed with the SEC on October 25, 2023)
10.24+	Compensation Agreement with Dr. William V. Williams, dated June 21, 2022 (incorporated by reference to Exhibit 10.23 to Form 10-K filed with the SEC on October 25, 2023)
10.25+	Employment Agreement with Giuseppe Del Priore, dated February 14, 2022 (incorporated by reference to Exhibit 10.24 to Form 10-K filed with the SEC on October 25, 2023)
10.26+	Employment Agreement with Gadi Levin, dated March 2, 2022 (incorporated by reference to Exhibit 10.25 to Form 10-K filed with the SEC on October 25, 2023)
10.27+	Employment Agreement with Miguel Lopez-Lago, dated May 26, 2022 (incorporated by reference to Exhibit 10.26 to Form 10-K filed with the SEC on October 25, 2023)

10.28	Exclusive License Agreement (incorporated by reference to Exhibit 10.27 to Form 10-K filed with the SEC on October 25, 2023)
10.29	Omnibus Equity Incentive Plan (incorporated by reference from Schedule I to the Proxy Statement for BriaCell Therapeutics Corp. 2023 Annual and Special Meeting of Shareholders, filed with the SEC on January 17, 2023).
10.30	Master Service and Technology Agreement dated May 9, 2023 (incorporated by reference to Exhibit 10.29 to Form 10-K filed with the SEC on October 25, 2023)
10.31	Stock Purchase Agreement dated May 12, 2023 (incorporated by reference to Exhibit 10.30 to Form 10-K filed with the SEC on October 25, 2023)
10.32	Arrangement Agreement dated May 24, 2023 (incorporated by reference to Exhibit 10.31 to Form 10-K filed with the SEC on October 25, 2023)
10.33	Placement Agency Agreement, dated May 14, 2024, by and between the Company and A.G.P./Alliance Global Partners (incorporated by reference to Exhibit 10.2 to our Form 8-K filed with the SEC on May 17, 2024)
10.34	Placement Agency Agreement, dated September 11, 2024, by and between the Company and ThinkEquity LLC (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on September 12, 2024)
	Placement Agency Agreement, dated October 1, 2024, by and between the Company and ThinkEquity LLC (incorporated by reference to Exhibit 10.1 to our Form 8-K filed with the SEC on October 2 , 2024)
21.1	List of Subsidiaries*
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
32.2	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**
97.1	Clawback Policy*
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
+	Indicates a management contract or compensatory plan or arrangement.
*	Filed herewith
**	Furnished herewith

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BRIACELL THERAPEUTICS CORP.

/s/ William V. Williams
Chief Executive Officer (Principal Executive Officer and Principal Accounting and Financial Officer)

October 28, 2024

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ William V. Williams William V. Williams	Chief Executive Officer, President and Director (Principal Executive Officer)	October 28, 2024
/s/ Gadi Levin Gadi Levin	Chief Financial Officer and Corporate Secretary (Principal Accounting and Financial Officer)	October 28, 2024
/s/ Jamieson Bondarenko Jamieson Bondarenko	Chairman of the Board of Directors	October 28, 2024
/s/ Vaughn C. Embro-Pantalony Vaughn C. Embro-Pantalony	Director	October 28, 2024
/s/ Marc Lustig Marc Lustig	Director	October 28, 2024
/s/ Martin E. Schmieg Martin E. Schmieg	Director	October 28, 2024
/s/ Rebecca Taub Rebecca Taub	Director	October 28, 2024
/s/ Jane A. Gross Jane A. Gross	Director	October 28, 2024

Consolidated Financial Statements

For the Years Ended July 31, 2024 and 2023
Expressed in United States Dollars

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of BriaCell Therapeutics Corp.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of BriaCell Therapeutics Corp. (the Company) as at July 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity (deficit), and cash flows for each of the years in the two-year period ended July 31, 2024, and the related notes (collectively referred to as the consolidated financial statements).

In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position at the Company as of July 31, 2024 and 2023, and the results of its consolidated operations and its consolidated cash flows for each of the years in the two-year period ended July 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Material Uncertainty Related to Going Concern

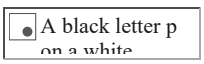
The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and has an accumulated deficit that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.



Chartered Professional Accountants
Licensed Public Accountants
We have served as the Company's auditor since 2015.
Mississauga, Canada
October 28 2024

BriaCell Therapeutics Corp
Consolidated Balance Sheets
As at July 31, 2024 and 2023
(Expressed in US Dollars, except share and per share data)

	July 31, 2024	July 31, 2023
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 862,089	$ 21,251,092
Amounts receivable and prepaid expenses	2,791,765	5,697,415
Total current assets	3,653,854	26,948,507
NON-CURRENT ASSETS:		
Investments	-	2
Equity investment in BC Therapeutics	418,490	-
Intangible assets, net	199,796	215,068
Property and equipment, net	388,175	-
Long term prepaid expenses	1,211,946	-
Total non-current assets	2,218,407	215,070
Total assets	$ 5,872,261	$ 27,163,577
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES:		
Trade payables	$ 7,170,781	$ 1,123,739
Accrued expenses and other payables	290,376	677,718
Total current liabilities	7,461,157	1,801,457
NON-CURRENT LIABILITIES:		
Warrant liability	1,096,036	29,139,301
Total non-current liabilities	$ 1,096,036	$ 29,139,301
CONTINGENT LIABILITIES AND COMMITMENTS		
SHAREHOLDERS' DEFICIT:		
Share Capital of no par value – Authorized: unlimited at July 31, 2024 and 2023; Issued and outstanding: 18,284,661 and 15,981,726 shares at July 31, 2024 and 2023, respectively	72,166,414	69,591,784
Share-based payment reserved	9,189,261	7,421,950
Warrant reserve	1,844,296	-
Accumulated other comprehensive loss	(138,684)	(138,684)
Non-controlling interest	(302,522)	-
Accumulated deficit	(85,443,697)	(80,652,231)
Total shareholders' deficit	(2,684,932)	(3,777,181)
Total liabilities and shareholders' deficit	$ 5,872,261	$ 27,163,577

These consolidated financial statements were approved and authorized for issue on behalf of the Board of Directors on October 28, 2024 by:

On behalf of the Board:

"Jamieson Bondarenko"	*"William Williams"*
Director	Director

The accompanying notes are an integral part of these consolidated financial statements.

BriaCell Therapeutics Corp
Consolidated Statements of Operations and Comprehensive Loss
For the Years Ended July 31, 2024 and 2023
(Expressed in US Dollars, except share and per share data)

	Year ended July 31,	
	2024	**2023**
Operating expenses:		
Research and development expenses	$ 27,177,807	15,336,638
General and administrative expenses	6,152,269	7,935,626
Total operating expenses	33,330,076	23,272,264
Operating loss	(33,330,076)	(23,272,264)
Financial income, net	262,566	850,340
Change in fair value of the warrant liability	28,242,472	2,119,530
Share of loss on equity investment	(106,510)	-
Net loss for the year	$ (4,931,548)	$ (20,302,394)
Net loss attributable to non-controlling interest	(140,082)	-
Net loss for the year attributable to BriaCell	(4,791,466)	(20,302,394)
Net loss per share attributable to BriaCell – basic and diluted	$ (0.29)	$ (1.30)
Weighted average number of shares used in computing net loss per share attributable to ordinary shareholders, basic and diluted	16,454,932	15,619,676

The accompanying notes are an integral part of these consolidated financial statements.

BriaCell Therapeutics Corp
Consolidated Statements of Changes in Shareholders' Equity (Deficit)
For the Years Ended July 31, 2024 and 2023
(Expressed in US Dollars , except share and per share data)

	Share capital		ADDITIONAL PAID IN	Warrant	ACCUMULATED OTHER COMPREHENSIVE	ACCUMULATED	Non-Controlling	TOTAL SHAREHOLDERS' EQUITY
	Number	Amount	CAPITAL	Reserve	INCOME (LOSS)	DEFICIT	Interest	(DEFICIT)
Balance, July 31, 2022	15,518,018	$65,589,293	$ 5,228,160	$ -	$ (138,684)	$ (60,349,837)	$ -	$ 10,328,932
Issuance of Options	-	-	2,193,790	-	-	-	-	2,193,790
Exercise of warrants	300	2,491	-	-	-	-	-	2,491
Issuance of shares	463,408	4,000,000	-	-	-	-	-	4,000,000
Net loss for the year	-	-	-	-	-	(20,302,394)	-	(20,302,394)
Balance, July 31, 2023	15,981,726	$69,591,784	$ 7,421,950	$ -	$ (138,684)	$ (80,652,231)	-	$ (3,777,181)
Instruments issued to minority shareholders at the arrangement date	-	-	(36,767)	-	-	-	(162,440)	(199,207)
Issuance of Options	-	-	1,804,078	-	-	-	-	1,804,078
Issuance of Units, net of issuance expenses	2,302,935	2,574,630	-	1,844,296	-	-	-	4,418,926
Net loss for the year	-	-	-		-	(4,791,466)	(140,082)	(4,931,548)
Balance, July 31, 2024	18,284,661	$72,166,414	$ 9,189,261	$1,844,296	$ (138,684)	$ (85,443,697)	(302,522)	$ (2,684,932)

The accompanying notes are an integral part of these consolidated financial statements.

BriaCell Therapeutics Corp
Consolidated Statements of Cash Flows
For the Years Ended July 31, 2024 and 2023
(Expressed in US Dollars, except share and per share data)

	Year ended July 31,	
	2024	2023
Cash flow from operating activities:		
Net loss for the year	$ (4,931,548)	$ (20,302,394)
Adjustments to reconcile loss to net cash used in operating activities:		
Amortization	15,271	15,271
Depreciation	68,626	-
Share-based compensation	1,804,078	2,193,790
Equity Losses	106,510	-
Change in fair value of warrants	(28,242,472)	(2,119,530)
Changes in assets and liabilities:		
(Increase) decrease in amounts receivable	(732,578)	5,230
Decrease (increase) in prepaid expenses	2,126,282	(4,397,597)
Increase in accounts payable	6,047,042	660,459
(Decrease) increase in accrued expenses and other payables	(387,339)	199,911
Net cash used in operating activities	(24,126,128)	(23,744,860)
Cash flow from investing activities:		
Purchase of property and equipment	(456,801)	-
Equity investment in BC Therapeutics (*)	(225,000)	-
Net cash used in investing activities	(681,801)	-
Cash flow from financing activities:		
Proceeds from exercise of warrants	-	1,594
Share and warrant buyback program	-	(47,294)
Proceeds from issuance of shares, net of issuance costs	4,418,926	4,000,000
Net cash provided by financing activities	4,418,926	3,954,300
Decrease in cash and cash equivalents	(20,389,003)	(19,790,560)
Cash and cash equivalents at beginning of year	21,251,092	41,041,652
Cash and cash equivalents at end of year	$ 862,089	$ 21,251,092

(*) In Addition, $125,000 was loaned to BC Therapeutics during the year ended July 31, 2023 and an additional $175,000 was loaned to BC Therapeutics between August 1, 2023 and December 20, 2023. The total amount ($300,000) was converted into an investment.

The accompanying notes are an integral part of these consolidated financial statements.

BriaCell Therapeutics Corp
Notes to the Consolidated Financial Statements
For the Years Ended July 31, 2024 and 2023
(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 1: GENERAL AND GOING CONCERN

a. BriaCell Therapeutics Corp. ("BriaCell" or the "Company") was incorporated under the Business Corporations Act (British Columbia) on July 26, 2006 and is listed on the Toronto Stock Exchange ("TSX") under the symbol "BCT". The Company also trades on the Nasdaq Capital Market ("NASDAQ") under the symbols "BCTX" and "BCTXW".

b. BriaCell is an immuno-oncology biotechnology company. The Company is currently advancing its Bria-IMT targeted immunotherapy program against end-stage breast cancer to Phase 3 study which has been approved by the FDA. BriaCell is also developing a personalized off-the-shelf immunotherapy, Bria-OTS™, and a soluble CD80 protein therapeutic which acts both as a stimulator of the immune system as well as an immune checkpoint inhibitor.

c. Going concern

The Company continues to devote substantially all of its efforts toward research and development activities. In the course of such activities, the Company has sustained operating losses and expects such losses to continue in the foreseeable future. The Company's accumulated deficit as of July 31, 2024 was $85,443,697 (July 31, 2023 - $80,652,231) and negative cash flows from operating activities during the year ended July 31, 2024 was $24,126,128 (July 31, 2023 - $23,744,860). The Company is planning to finance its operations by exploring additional sources of capital and financing, while managing its existing working capital resources. The Company's ability to continue as a going concern is dependent upon its ability to attain future profitable operations and to obtain the necessary financing to meet its obligations arising from normal business operations when they come due. The uncertainty of the Company's ability to raise such financial capital casts substantial doubt on the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should the Company not be able to continue as a going concern. See note 15(c,d) for details of an $8.5 million and $5.0 million offering that was completed in September 2024 and October 2024, respectively.

d. The Company has two wholly-owned U.S. subsidiaries: (i) BriaCell Therapeutics Corp. ("BTC"), which was incorporated in April 3, 2014, under the laws of the state of Delaware, and (ii) BTC has a wholly-owned subsidiary, Sapientia Pharmaceuticals, Inc. ("Sapientia"), which was incorporated in September 20, 2012, under the laws of the state of Delaware. The Company also has one Canadian subsidiary: BriaPro Therapeutics Corp, ("BriaPro") which was incorporated on May 15, 2023, under the Business Corporations Act (British Columbia). See also note 1e. (Sapientia and BTC and BriaPro together, the "Subsidiaries")

The Company has one operating segment and reporting unit.

e. On August 31, 2023, the Company closed a plan of arrangement spinout transaction (the "Arrangement") pursuant to which certain pipeline assets of the Company, including Bria-TILsRx™ and protein kinase C delta (PKCδ) inhibitors for multiple indications including cancer (the "BriaPro Assets"), were spun-out to BriaPro Therapeutics Corp. ("BriaPro"), resulting in a 2/3rd owned subsidiary of the Company with the remaining 1/3rd held by BriaCell shareholders ("BriaCell Shareholders").

Pursuant to the terms of the Arrangement, BriaPro has acquired the entire right and interest in and to the BriaPro Assets in consideration for the issuance by BriaPro to the Company of BriaPro common shares. Under the terms of the Arrangement, for each BriaCell share held immediately prior to closing, BriaCell Shareholders receive one (1) common share of BriaPro, and one (1) new common share of BriaCell (retiring their old share) having the same terms and characteristics as the existing BriaCell common shares. The Company will remain listed on the NASDAQ Stock Market and Toronto Stock Exchange, and BriaPro is an unlisted reporting issuer in Canada.

Immediately following the closing of the Arrangement, the Company controls 2/3rd of the BriaPro common shares representing approximately 66.6% of the issued and outstanding common shares of BriaPro.

As a result of the Arrangement, there are 47,945,178 BriaPro common shares issued and outstanding. The Company now beneficially owns or controls approximately 31,963,452 BriaPro common shares, representing 2/3rd of the issued and outstanding BriaPro common shares.

Pursuant to the Arrangement, each BriaCell warrant in issuance at the time of the Arrangement shall, in accordance with its terms, entitle the holder thereof to receive, upon the exercise thereof, one BriaCell Share and one BriaPro Share for the original exercise price. Warrants issued by the Company, subsequent to the Arrangement are not subject to the terms above.

Upon the exercise of BriaCell Warrants, BriaCell shall, as agent for BriaPro, collect and pay to BriaPro an amount for each one (1) BriaPro Share so issued that is equal to the exercise price under the BriaCell Warrant multiplied by the fair market value of one (1) BriaPro Share at the Effective Date divided by the total fair market value of one (1) BriaCell Share and one (1) BriaPro Share at the Effective Date ("BriaPro Warrant Shares").

Pursuant to the Arrangement, all Briacell option holders received the same amount of BriaPro options ("BriaPro Option") and under the BriaPro incentive plan. The exercise price of the BriaCell options was apportioned between the BriaCell options and the BriaPro options, as follows:

Each one (1) BriaPro Option to acquire one (1) Share shall have an exercise price equal to the product obtained by multiplying the original exercise price of the BriaCell Option by the quotient obtained by dividing (A) the fair market value of a BriaPro Share at the Effective Date by (B) the aggregate fair market value of a BriaCell Share and a BriaPro Share at the Effective Date.

Pursuant to the Arrangement, all BriaCell Restricted Shares Units ("RSU") holders received the same amount of BriaPro RSU's under the BriaPro incentive plan.

Transition Services Agreement

On August 31, 2023, the Company and BriaPro executed a transition services agreement (the "Agreement"), pursuant to which BriaCell will provide certain research and development and head office services (the "Services") to BriaPro for a fixed monthly fee of $20,000.

Briacell and BriaPro acknowledged the transitional nature of the Services and accordingly, as promptly as practicable, BriaPro agreed to use commercially reasonable efforts to transition each Service to its own internal organization or to obtain alternate third party providers to provide the Services.

In accordance with US GAAP's Accounting Standards Codification 505 "Equity", the Arrangement was determined to be a spinoff of nonmonetary assets which did not constitute a business. However, since the assets were transferred to an entity under the Company's control, the assets is being recorded on the Company's basis (carry value) and not at fair market value.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements:

The Company's consolidated financial statements have been prepared in accordance with the United States generally accepted accounting principles (U.S. GAAP) as set forth in the Financial Accounting Standards Board (the "FASB") Accounting Standards Codification (ASC).

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

b. Use of estimates, assumptions and judgements:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company's management believes that the estimates, judgment and assumptions used are reasonable based upon information available at the time they are made. These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities at the dates of the consolidated financial statements, and the reported amount of expenses during the reporting periods. Actual results could differ from those estimates.

Going Concern

Preparation of the consolidated financial statement on a going concern basis, which contemplates the realization of assets and payments of liabilities in the ordinary course of business. Should the Company be unable to continue as a going concern, it may be unable to realize the carrying value of its assets, including its intangible assets and to meet its liabilities as they become due.

Warrants and options

The Company uses the Black-Scholes option-pricing model to estimate the fair value of options at the grant date, and the warrant liability at the grant date and each reporting period date. The key assumptions used in the model are the expected future volatility in the price of the Company's shares and the expected life of the warrants.

Income Taxes

The Company accounts for income taxes in accordance with Accounting Standard Codification 740, Income Taxes ("FASB ASC 740"), on a tax jurisdictional basis. The Company files income tax returns in the United States.

Deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the tax bases of assets and liabilities and the consolidated financial statements reported amounts using enacted tax rates and laws in effect in the year in which the differences are expected to reverse. A valuation allowance is provided against deferred tax assets when it is determined to be more likely than not that the deferred tax asset will not be realized.

Provision for Income Taxes. Management accounts for income taxes by estimating future tax effects of temporary differences between the tax and book basis of assets and liabilities considering the provisions of enacted tax laws. The application of income tax law is inherently complex. Laws and regulations in this area are voluminous and are often ambiguous. As such, management is required to make many subjective assumptions and judgments regarding the Corporation's income tax exposures, including judgments in determining the amount and timing of recognition of the resulting deferred tax assets and liabilities, including projections of future taxable income. Interpretations of and guidance surrounding income tax laws and regulations change over time. As such, changes in management's subjective assumptions and judgments can materially affect amounts recognized in the Consolidated balance sheet and Consolidated Statements of Operations and Comprehensive Loss

Intangible assets

Intangible assets are tested for impairment annually or more frequently if there is an indication of impairment. The carrying value of intangibles with definite lives is reviewed each reporting period to determine whether there is any indication of impairment. If there are indications of impairment, the impairment analysis is completed and if the carrying amount of an asset exceeds its recoverable amount, the asset is impaired and impairment loss is recognized.

Prepaid expenses

The Company has prepaid certain expenses in respect of its pivotal phase III trial and estimates the period over which such expenses will be incurred. As of July 31, 2024, the Company revised its estimate of the time to completion in respect of this trial. Amounts estimated to be expenses in more than 12 months have been classified to long-term prepaid expenses.

The useful life of property and equipment

Property and equipment are depreciated over their useful lives. Useful lives are based on management's estimates of the period that the assets will be used which are periodically reviewed for continued appropriateness. Changes to estimates can result in significant variations in the amounts charged to the consolidated statement of operations and comprehensive loss in specific periods.

Investment equity method

Investments in entities over which the Company does not have a controlling financial interest but has significant influence are accounted for using the equity method, with the Company's share of losses reported in the loss from equity method investments on the statements of operation and comprehensive loss. The Company has a 51.2% interest in BC Therapeutics. Management evaluates whether it has control over the investee in accordance with the guidance of ASC 810, which requires judgment to assess factors such as power over significant activities of the investee, exposure to variable returns, and the ability to affect those returns. Based on this evaluation, management determines whether control or

significant influence is present for accounting purposes.

c. Principal of consolidation:

The consolidated financial statements include the accounts of the Company and its Subsidiaries. All intercompany balances and transactions have been eliminated upon consolidation.

d. Consolidated financial statements in U.S dollars:

The functional currency is the currency that best reflects the economic environment in which the Company and its subsidiary operates and conducts their transactions. The functional currency of the Company and its subsidiaries is the U.S. dollar.

Accordingly, monetary accounts maintained in currencies other than the U.S. dollar are remeasured into U.S. dollars at each reporting period end in accordance with ASC No. 830 “Foreign Currency Matters.” All transaction gains and losses of the remeasured monetary balance sheet items are reflected in the statements of operations as financing income or expenses as appropriate.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

e. Cash and cash equivalents:

Cash equivalents are short-term highly liquid deposits that are readily convertible to cash with original maturities of three months or less, at the date acquired, and investments with maturities of longer than three months where the investment can be liquidated before the maturity date without a significant penalty.

f. Equity method investments:

Investments in entities over which the Company does not have a controlling financial interest but has significant influence, are accounted for using the equity method, with the Company's share of losses reported in loss from equity method investments on the statements of operation and comprehensive loss. Equity method investments are recorded at cost, plus the Company's share of undistributed earnings or losses, and impairment, if any, within interest in equity investees on the statements of financial position.

g. Property and Equipment, net:

Property and equipment with individual values of over $2,500 are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

Laboratory equipment	20%

h. Intangible assets, net:

Separately acquired intangible assets are measured on initial recognition at cost including directly attributable costs. Intangible assets acquired in a business combination are measured at fair value at the acquisition date. Expenditures relating to internally generated intangible assets, excluding capitalized development costs, are recognized in profit or loss when incurred.

Intangible assets with finite useful lives are amortized over their useful lives and whenever there is an indication that the asset may be impaired. The evaluation is performed at the lowest level for which identifiable cash flows are largely independent of the cash flows of other assets and liabilities. Recoverability of these group of assets is measured by a comparison of the carrying amounts to the future undiscounted cash flows the group of assets is expected to generate. If such review indicates that the carrying amount of intangible assets is not recoverable, the carrying amount of such assets is reduced to fair value.

The amortization period and the amortization method for an intangible asset are reviewed at least at each year end.

Intangible assets with indefinite useful lives are not systematically amortized and are tested for impairment annually, or whenever there is an indication that the intangible asset may be impaired. The useful life of these assets is reviewed annually to determine whether their indefinite life assessment continues to be supportable. If the events and circumstances do not continue to support the assessment, the change in the useful life assessment from indefinite to finite life is accounted for prospectively as a change in accounting estimate and on that date the asset is tested for impairment. Commencing from that date, the asset is amortized systematically over its useful life.

The details of intangible assets are as follows:

	Patents
Useful life	20 years
Amortization method	Straight-line
In-house development or purchase	Purchase

For the years ended July 31, 2024 and 2023, no indicators of impairment have been identified.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. Research and Development expenses:

Research and development expenses are recognized in the consolidated statements of operations and comprehensive loss when incurred. Research and development expenses consist of intellectual property, development and production expenditures.

Government grants are recognized when there is reasonable assurance that the grants will be received, and the Company will comply with the conditions. The grants are offset against the related research and development expenditure.

j. Fair value of financial instruments:

The accounting guidance for fair value provides a framework for measuring fair value, clarifies the definition of fair value, and expands disclosures regarding fair value measurements. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value as follows:

Level 1 — Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 — Observable inputs that are based on inputs not quoted on active markets but corroborated by market data.

Level 3 — Unobservable inputs are used when little or no market data are available.

The carrying amounts of cash and cash equivalents, subscriptions receipts, trade payables and accrued expenses and other payables approximate their fair value due to the short-term maturity of such instruments.

The carrying amount of warrant liabilities is recorded at the fair value at each reporting period.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

k. Leases:

The Company accounts for leases according to ASC 842, "Leases". The Company determines if an arrangement is a lease and the classification of that lease at inception based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the Company obtains the right to substantially all the economic benefits from the use of the asset throughout the period, and (3) whether the Company has a right to direct the use of the asset. An ROU asset represents the right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease agreement. An ROU asset is measured based on the discounted present value of the remaining lease payments, plus any initial direct costs incurred and prepaid lease payments, excluding lease incentives. The lease liability is measured at lease commencement date based on the discounted present value of the remaining lease payments. The implicit rate within the operating leases is generally not determinable, therefore the Company uses the Incremental Borrowing Rate ("IBR") based on the information available at commencement date in determining the present value of lease payments. The Company's IBR is estimated to approximate the interest rate for collateralized borrowing with similar terms and payments and in economic environments where the leased asset is located. An option to extend the lease is considered in connection with determining the ROU asset and lease liability when it is reasonably certain that the Company will exercise that option. An option to terminate is considered unless it is reasonably certain that the Company will not exercise the option.

The Company elected the practical expedient for lease agreements with a term of twelve months or less and does not recognize right-of-use ("ROU") assets and lease liabilities in respect of those agreements. The Company also elected the practical expedient to not separate lease and non-lease components for its leases.

l. Share-based compensation:

The Company accounts for share-based compensation in accordance with ASC No. 718, "Compensation – Stock Compensation", which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the award is recognized as an expense over the requisite service periods, which is the vesting period of the respective award, on a straight-line basis when the only condition to vesting is continued service.

The Company has selected the Black-Scholes option-pricing model as the most appropriate fair value method for its option awards. The Company recognizes forfeitures of equity-based awards as they occur. Restricted share units use the share price on the grant date to determine the fair value of the restricted share unit award.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. Income Taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes", which prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, to reduce deferred tax assets to their estimated realizable value, if needed.

ASC 740 offers a two-step approach for recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate settlement. As of July 31, 2024, and 2023 no liability for unrecognized tax benefits was recorded as a result of ASC 740.

n. Basic and diluted net loss per Share:

The Company's basic net loss per share is calculated by dividing net loss attributable to ordinary shareholders by the weighted-average number of shares of ordinary shares outstanding for the period, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive ordinary shares are anti-dilutive.

o. Recently issued and adopted accounting standards:

As an "emerging growth company," the Jumpstart Our Business Startups Act ("JOBS Act") allows the Company to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. The Company has elected to use this extended transition period under the JOBS Act. The adoption dates discussed below reflects this election.

1. In July 2023, the FASB issued 2023-03 — Presentation of Financial Statements (Topic 205), Income Statement — Reporting Comprehensive Income (Topic 220), Distinguishing Liabilities from Equity (Topic 480), Equity (Topic 505), and Compensation — Stock Compensation (Topic 718): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 120, SEC Staff Announcement at the March 24, 2022, EITF Meeting, and Staff Accounting Bulletin Topic 6.B, Accounting Series Release 280 — General Revision of Regulation S-X: Income or Loss Applicable to Common Stock (SEC Update). The adoption of this standard on August 1, 2023, did not result in amended disclosures in the Company's consolidated financial statements, nor did this standard have a material impact the Company's results of operations.

2. In December 2023, the FASB issued ASU 2023-09 - *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* This standard modifies the rules on income tax disclosures to require entities to disclose specific categories in the rate reconciliation, the income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. ASU 2023-09 also requires entities to disclose their income tax payments to international, federal, state, and local jurisdictions. The ASU is effective for years beginning after December 15, 2024, but early adoption is permitted. This ASU should be applied on a prospective basis, although retrospective application is permitted. The Company is currently evaluating the impact of this standard on its financial statements and disclosures.

3. In March 2024, the FASB issued ASU 2024-01 - *Compensation—Stock Compensation (Topic 718): Scope Application of Profits Interest and Similar Awards.* This standard clarifies whether profits interest and similar awards fall within the scope of stock-based compensation guidance as defined in ASC Topic 718, introducing examples to demonstrate this. The ASU includes scenarios where profits interest awards are classified as equity instruments or liability awards and situations where they fall outside ASC Topic 718, being accounted for under ASC Topic 710. The ASU is effective for years beginning after December 15, 2024, but early adoption is permitted. This ASU should be applied on a prospective basis, although retrospective application is permitted. The Company is currently evaluating the impact of this standard on its financial statements and disclosures.

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 3: Amounts receivable and prepaid expenses

	July 31, 2024	July 31, 2023
Directors and officers insurance	$ 632,657	$ 717,742
Prepaid expense (a)	1,322,122	4,835,800
Subscription receipt (b)	736,359	-
Other prepaids	100,627	143,873
	$ 2,791,765	$ 5,697,415

(a) Prepaid expenses as of July 31, 2024 include amounts paid to certain vendors in respect of the Company's ongoing pivotal phase III trial study. These amounts are amortized over the period of the clinical trial. Prepaid expenses estimated to be expensed within 12 months amount to $1,322,122 and are included in current assets, whist the balance, extending longer than 12 months, amounts to $1,211,946 and is included in non-current assets under long-term prepaid expenses.

(b) The subscription receipt relates to the May 2024 Offering (see note 9(b)(ii)(1)). All the funds have been received subsequent to the balance sheet date.

NOTE 4: INVESTMENT IN BC THERAPEUTICS INC.

On December 21, 2021, the Company and BC Therapeutics, Inc. ("BC Therapeutics" or "the Investee") entered a share purchase agreement ("SPA"), pursuant to which the Company initially provided a loan of $300,000 to BC Therapeutics, with no interest to be paid. Subsequently, in accordance with the SPA, this loan was converted into an equity investment in BC Therapeutics at a rate of $1.25 per share, resulting in a 37.5% ownership interest ("Initial Investment").

Pursuant to the SPA ("Initial Investment"), Briacell also received two options to invest an additional $225,000 per option at $1.25 per BC Therapeutics share. The first option expires on February 15, 2024 ("First BC Therapeutics Option") and the second option expires on June 30, 2024 ("Second BC Therapeutics Options", together, the "BC Therapeutic Options"). In accordance with ASC 321 and ASC 815, the BC Therapeutics Options were valued at $76,350 in accordance with the Black Scholes Option Price Model, using the following assumptions: Share price: $1.25, Exercise price: $1.25, Dividend yield: 0%, Risk free interest rate: 4.902%, Volatility: 100%.

BC Therapeutics has a board of four representatives, with two representatives appointed by BriaCell and two representatives appointed by the existing shareholders. All significant decisions related to BC Therapeutics require the approval of at least a majority of the board members.

On February 1, 2024, the Company exercised the First BC Therapeutics Option and currently holds 51.2% of BC Therapeutics. The value of the BC Therapeutics Options was updated to consider the effect of the exercise of the First BC Therapeutics Option. Consequently, the fair value of the First BC Therapeutics Option, $35,964, has been reclassified to the investment. See also note 15(a) for details of transactions subsequent to the year end.

In accordance with ASC 810, the Company continues to account for the investment under the equity method of accounting as the Company does not exercise control over BC Therapeutics.

Changes in the Company's equity investment in BC Therapeutics is summarized as follows:

Balance – August 1, 2023	$ -
Funding (including the value of the BC Therapeutics Options)	**525,000**
Share of losses:	(106,510)
Balance – July 31, 2024	**$ 418,490**

The following amounts represent the Company's 51.2% share of the assets of BC Therapeutics:

	As of July 31, 2024
Current assets: Cash	$ 32,810
Net assets	**$ 32,810**

NOTE 5: INTANGIBLE ASSETS, NET

Acquired intangible assets with finite lives consisted of the following as of July 31, 2024 and 2023:

	July 31, 2024	July 31, 2023
Patents	$ 305,130	$ 305,130

Gross intangible assets	305,130	305,130
Less – accumulated amortization	(105,334)	(90,062)
Intangible assets, net	$ 199,796	$ 215,068

The attributable intellectual property relates to Sapientia's various patents, which the Company is amortizing over 20 years, consistent with its accounting policy.

Amortization expenses for the years ended July 31, 2024 and 2023, were $15,271 and $15,271, respectively.

The estimated future amortization expense of intangible assets as of July 31, 2024 is as follows:

2025	$ 15,271
2026	15,271
2027	15,271
2028	15,271
2029 and thereafter	138,712
	$ 199,796

See also note 1(e) regarding the transfer of the intangible asset.

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 6: PROPERTY AND EQUIPEMENT, NET

During the year ended July 31, 2024, the Company purchased certain laboratory equipment in the gross amount of $456,801.

	Laboratory equipment
Cost:	
As of August 1, 2023	$ -
Additions	456,801
Disposals	-
As of July 31, 2024	$ 456,801
Accumulated depreciation:	
As of August 1, 2023	$ -
Depreciation	68,626
As of July 31, 2024	$ 68,626
Net Book Value:	
As of July 31, 2024	$ 388,175
As of July 31, 2023	$ -

NOTE 7: CONTINGENT LIABILITIES AND COMMITMENTS

a. BriaPro Warrants

Upon the exercise of BriaCell Warrants, BriaCell shall, as agent for BriaPro, collect and pay to BriaPro an amount based on an agreed formula (detailed in note 1(e)). As of July 31, 2024, this amount totaled of up to $241,164 and is eliminated on consolidation.

b. Lease

The Company is currently in a 12-month commitment for office and lab space in Philadelphia, PA, costing the company approximately $38,110 per month. The lease is set to expire on August 31, 2024, with a month-to-month extension thereafter.

NOTE 8: FAIR VALUE MEASUREMENTS

The following table presents information about our financial instruments that are measured at fair value on a recurring basis as of July 31, 2024 and 2023:

	Fair Value Measurements at					
	July 31, 2024			July 31, 2023		
	Level 1	Level 2	Total	Level 1	Level 2	Total
Financial Assets:						
Cash and cash equivalents	$ 862,089	$ -	$ 862,089	$21,251,092	$ -	$21,251,092
Total assets measured at fair value	$ 862,089	$ -	$ 862,089	$21,251,092	$ -	$21,251,092
Financial liabilities:						
Warrants liability	760,657	335,379	1,096,036	9,742,023	19,397,278	29,139,301
Total liabilities measured at fair value	$ 760,657	335,379	1,096,036	$ 9,742,023	19,397,278	29,139,301

The Company classifies its cash equivalents and the liability in respect of publicly traded warrants within Level 1 because they are valued using the quoted market prices in active markets.

The fair value of the warrant liability for non-public warrants is measured using inputs other than quoted prices included in Level 1 that are observable for the liability either directly or indirectly, and thus are classified as Level 2 financial instruments.

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 9: SHAREHOLDERS' EQUITY

a. Authorized share capital

The authorized share capital consists of an unlimited number of common shares with no par value ("Share").

b. Issued share capital

(i) The Company issued the following shares during the year ended July 31, 2023:

1. On April 14, 2023, 300 warrants with an exercise price of $5.31 were exercised for gross proceeds of $1,594. The Company issued 300 shares in respect of the exercise of these warrants.

2. On May 12, 2023, the Company issued 463,408 Shares to Prevail Partners, LLC at a price per share of $8.63, resulting in aggregate gross proceeds of $4,000,000.

(ii) The Company issued the following shares during the year ended July 31, 2024:

1. On May 17, 2024, the Company closed a registered direct offering with healthcare-focused institutional investors, certain existing investor and a director of the Company for the purchase and sale of 2,302,935 common shares of the Company and 100,000 pre-funded warrants with an offering price of $1.1999, an exercise price of $0.0001 and may be exercised at any time in the future, and warrants to purchase up to an aggregate of 2,402,935 common shares of the Company ("May 2024 Warrants") for aggregate gross proceeds of approximately $5.0 million before deducting placement agent fees and other offering expenses (the "May 2024 Offering"). Each common share (or pre-funded warrant in lieu thereof) was sold together with one warrant to purchase one common share at a combined purchase price of $2.00 to the institutional investors and $2.215 to the existing investor and director of the Company. The May 2024 Warrants have an exercise price of $2.11 per share, will become exercisable six months from the date of issuance and expire five years from the initial exercise date. In addition, the Company issued 50,000 placement agent warrants with the same terms as the May 2024 Warrants.

   The prefunded warrants were exercised on August 7, 2024 – see note 15(b).

   The fair value of the 2,452,935 May 2024 Warrants had a fair value of $2,020,207 using the Black-Scholes option price model, with the following assumptions: share price - $1.18; exercise price - $2.11; expected life – 5.5 years; annualized volatility - 118%; dividend yield - 0%; risk free rate – 4.71%, non-marketability discount – 13.13%.

   The amount was credited to the warrant reserve at the date of the May 2024 Offering.

c. Share Purchase Warrants

A summary of changes in share purchase warrants for the years ending July 31, 2024 and 2023 is presented below:

	Number of options outstanding	Weighted average exercise price (*)
Balance, July 31, 2022	**8,137,686**	**$ 5.76**
Exercised	(300)	(5.31)
Repurchased and cancelled	(15,736)	(5.31)
Balance, July 31, 2023	**8,121,650**	**$ 5.76**
Granted in the May 2024 Offering	2,402,935	**2.11**
Balance, July 31, 2024	**10,524,585**	**$ 4.92**

(*) See note 7(a).

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 9: SHAREHOLDERS' EQUITY (Cont.)

As of July 31, 2024, warrants outstanding were as follows:

Number of Warrants outstanding as of July 31, 2024		Exercise Price	Number of Warrants Exercisable as of July 31, 2024	Expiry Date
51,698	$	3.93	51,698	November 16, 2025
3,896,809	$	5.31	3,896,809	February 26, 2026 – April 26, 2026
4,173,143	$	6.19	4,173,143	December 7, 2026
2,402,935	$	2.11	-	November 17, 2029
10,524,585			**8,121,650**	

e) Compensation Warrants

A summary of changes in compensation warrants for the years ended July 31, 2024 and 2023 is presented below:

	Number of warrants outstanding	Weighted average exercise price (*)
Balance, July 31, 2022 and 2023	**46,652**	**5.66**
Granted in the May 2024 Offering	50,000	2.32
Balance, July 31, 2024	**96,652**	**$ 3.92**

(*) See note 7(a).

As of July 31, 2024, compensation warrants outstanding were as follows:

Number of Warrants		Exercise Price	Exercisable At July 31, 2024	Expiry Date
4,890	$	3.91	4,890	November 16, 2025
17,074	$	5.31	17,074	February 26, 2026
24,688	$	6.19	24,688	June 7, 2026
50,000	$	2.32	-	May 17, 2029
96,652			**46,652**	

f) **Warrant liability continuity**

(i) The following table presents the summary of the changes in the fair value of the warrants recorded as a liability on the Balance Sheet (*):

	Warrants liability
Balance as of July 31, 2022	$ 31,307,022
Exercise of warrants	(897)
Warrant buyback program	(47,294)
Change in fair value during the year	(2,119,530)
Balance as of July 31, 2023	29,139,301
Fair value of BriaPro Warrant Shares at Effective Date (note 1(e))	199,207
Change in fair value during the year	(28,242,472)
Balance as of July 31, 2024	$ 1,096,036

(*) Certain warrants were issued prior to August 1, 2022 in respect of public offerings and private placements that contain terms that require the warrants to be recorded as a liability at fair value under US GAAP. As a result, these warrants are valued at the end of each reporting period. For the year ended July 31, 2024, the Company recorded a gain on the revaluation of the total warrant liability of $28,242,472 in the consolidated statements of operations and comprehensive loss.

The key inputs used in the valuation of the of the warrant as of July 31, 2024 and at July 31, 2023 and on the issuance dates, were as follows:

	February 26, 2021 (Issuance	April 12, 2021 (Issuance	July 31, 2024	July 31, 2023

	date)	date)		
Share price	$ 3.40	$ 3.92	$ 0.75	$ 6.69
Exercise price	$ 5.31	$ 5.31	5.31-6.19	$ 5.31-6.19
Expected life (years)	5.00	5.00	1.57-2.35	2.58-3.35
Volatility	100%	100%	77-79%	100%
Dividend yield	0%	0%	0%	0%
Risk free rate	0.88%	0.97%	4.27%	4.51%

The key inputs used in the valuation of the of the BriaPro Warrant Shares as of July 31, 2024 were as follows:

	July, 31 2024	August 31, 2023 (Effective Date)
Share price	$ 0.0365	$ 0.0365
Exercise price	$ 0.0206-0.0308	$ 0.0206-0.0308
Expected life (years)	1.30-2.35	2.21-3.27
Volatility	79-781%	100%
Dividend yield	0%	0%
Risk free rate	3.46%	4.40%

NOTE 10: SHARE-BASED COMPENSATION

On August 2, 2022, the Company approved an omnibus equity incentive plan ("Omnibus Plan"), which will permit the Company to grant incentive stock options, preferred share units, restricted share units ("RSU's"), and deferred share units (collectively, the "Awards") for the benefit of any employee, officer, director, or consultant of the Company or any subsidiary of the Company. The maximum number of shares available for issuance under the Omnibus Plan shall not exceed 15% of the issued and outstanding Shares, from time to time, less the number of Shares reserved for issuance under all other security-based compensation arrangements of the Company, including the existing Stock Option Plan. On February 9, 2023, the Omnibus Plan was approved by the shareholders.

a. The following table summarizes the number of options granted under the Stock Option Plan for the year ended July 31, 2024 and related information:

	Number of options	Weighted average exercise price (*)	Weighted average remaining contractual term (in years)	Aggregate intrinsic value
Balance as of July 31, 2022	1,490,300	$ 6.20	4.09	$ 447,090
Granted (i)	641,100	6.16	4.63	
Balance as of July 31, 2023	2,131,400	6.19	3.55	1,065,700
Balance as of July 31, 2024	2,131,400	6.16	2.52	-
Exercisable as of July 31, 2023	1,585,655	$ 6.18	3.19	$ 808,684
Exercisable as of July 31, 2024	1,961,150	$ 6.17	2.41	$ -

(i) The 641,100 options granted to directors and employees during the year ended July 31, 2023 vest quarterly over the two years from grant date.

(ii) The weighted-average grant date per-share fair value of stock options granted during 2024 and 2023 was $nil and $4.72, respectively. As of July 31, 2024, there are $786,570 of total unrecognized costs related to share-based compensation that is expected to be recognized over a period of up to 0.75 years.

(*) certain options are exercisable in Canadian dollars and translated to US Dollars at year end.

b. The following table lists the inputs to the Black-Scholes option-pricing model used for the fair value measurement of equity-settled share options for the above Options Plans granted for the years 2024 and 2023:

	Year ended July 31,	
	2024 (*)	2023
Dividend yield	n/a	0%
Expected volatility of the share prices	n/a	100%
Risk-free interest rate	n/a	3.99%-4.23%
Expected term (in years)	n/a	5

(*)There were no options grants during the year end July 31, 2024.

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 10: SHARE-BASED COMPENSATION (Cont.)

c. The following table summarizes information about the Company's outstanding and exercisable options granted to employees as of July 31, 2024

Exercise price	Options outstanding as of July 31, 2024	Options exercisable as of July 31, 2024	Weighted average remaining contractual term (years)	Expiry Date
$ 6.03	440,000	275,000	3.89	June 20, 2028
$ 7.16	21,000	15,750	3.58	February 27, 2028
$ 6.10	180,100	180,100	3.01	August 02, 2027
$ 4.71	31,000	31,000	2.81	May 20, 2027
$ 7.51	150,000	150,000	2.54	February 16, 2027
$ 8.47	524,700	524,700	2.45	January 13, 2027
$ 7.22	12,600	12,600	2.25	November 01, 2026
$ 5.74	100,000	100,000	2.09	September 01, 2026
$ 4.24	60,000	60,000	1.72	April 19, 2026
$ 4.24	612,000	612,000	1.66	March 29, 2026
	2,131,400	1,961,150		

d. As result of the Arrangement, 2,131,400 BriaPro Options were issued and are outstanding as of July 31, 2024:

Exercise Price	Options outstanding as of July 31, 2024	Options exercisable as of July 31, 2024	Expiry Date
$ 0.0933	440,000	275,000	June 20, 2028
$ 0.1108	21,000	15,750	February 27, 2028
$ 0.0984	180,100	180,100	August 02, 2027
$ 0.0729	31,000	31,000	May 20, 2027
$ 0.1162	150,000	150,000	February 16, 2027
$ 0.1310	524,700	524,700	January 13, 2027
$ 0.1165	12,600	12,600	November 01, 2026
$ 0.0888	100,000	100,000	September 01, 2026
$ 0.0656	60,000	60,000	April 19, 2026
$ 0.0656	612,000	612,000	March 29, 2026
	2,131,400	1,961,150	

e. Restricted Share Units

The following table summarizes the number of RSU's granted to directors under the Omnibus Plan for year ended July 31, 2024:

	Number of RSU's outstanding	Aggregate intrinsic value
Balance, July 31, 2023	**19,200**	**$ 128,448**
Balance, July 31, 2024	**19,200**	**$ 14,400**

f. The total share-based compensation expense related to all of the Company's equity-based awards, recognized for the years ended July 31, 2024 and 2023 is comprised as follows:

	Year ended July 31,	
	2024	2023
Research and development expenses	$ 734,986	$ 1,072,592
General and administrative expenses	1,069,092	1,121,198
Total share-based compensation	$ 1,804,078	$ 2,193,790

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 11: TAXES ON INCOME

a. Components of income taxes excluding cumulative effects of changes in accounting principles, other comprehensive income, and equity in net results of affiliated companies accounted for after-tax for the years ended July 31 were as follows:

b. The Company recorded loss before taxes on income as follows:

	Year ended July 31,	
	2024	**2023**
Domestic	$ 23,946,952	$ (2,469,999)
Foreign	(28,878,500)	(17,832,395)
	$ (4,931,548)	$ (20,302,394)

c. The reconciliation of the combined Canadian federal and provincial statutory income tax rate of 27% (2023 - 27%) to the effective tax rate is as follows:

	Year ended July 31,	
	2024	**2023**
Net loss before recovery of income taxes	$ (4,931,548)	$ (20,302,394)
Expected income tax (recovery) expense	(1,331,518)	(5,481,650)
Tax rate changes and effect of taxes of subsidiaries at foreign rates	1,467,021	1,068,270
Share-based compensation and other non-deductible expenses	1,697,204	622,220
R&D Credits	(3,903,153)	-
Effect of spin-out transaction	(297,781)	
Valuation allowance	2,368,228	3,791,160
Income tax (recovery)	$ -	$ -

d. The Company had no income tax expense for the years ended July 31, 2024, and 2023, due to its history of operating losses and valuation allowances.

e. Significant components of the Company's deferred tax assets are as follows:

	July 31,	
	2024	**2023**
Deferred Tax Assets:		
Property and equipment	$ 731	730
Marketable Securities	15,678	11,760
Intellectual property	256,741	-
Warrant liability	-	3,776,710
Share issuance costs	376,978	734,300
Investment in BC Therapeutics	19,172	-
Operating tax losses carried forward	4,850,799	3,842,320
Operating tax losses carried forward- USA	5,545,125	4,913,950
Research and Development	10,879,373	2,685,825
Total deferred tax assets	21,944,597	15,965,594
Valuation allowance	(18,034,710)	(15,920,430)
Net deferred tax assets	$ 3,909,886	$ 45,160
Deferred Tax Liability:		
Intellectual Property	$ -	$ (45,160)
Warrant liability	(3,848,762)	-
Property, plant, and equipment	(61,125)	-
Total net deferred tax liabilities	(3,909,886)	(45,160)
Valuation allowance	-	-
Net deferred tax assets (liabilities)	$ -	$ -

f. The Company has net deferred tax assets relating primarily to net operating loss ("NOL") carryforwards, research and development, and share issuance costs. Subject to certain limitations, the Company may use these deferred tax assets to offset taxable income in future periods. Due to the Company's history of losses and uncertainty regarding future earnings, a full valuation allowance has been recorded against the Company's deferred tax assets, as it is more likely than not that such assets will not be realized. The net change in the total valuation allowance for the year ended July 31, 2024, was $1,792,500.

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 11: TAXES ON INCOME (Cont.)

At July 31, 2024, the Company had US federal NOL carryforwards of approximately $26,405,000. The federal net operating losses have expiry periods ranging between 2033 and indefinitely. The Company also has Canadian net operating loss carryovers of approximately $17,965,000 as of July 31, 2024. The Canadian net operating losses have expiry periods ranging between 2035 and 2044.

The Company has adopted the provisions of ASC 740-10, which clarifies the accounting for uncertain tax positions. ASC 740-10 requires that the Company recognize the impact of a tax position in its financial statements if the position is more likely than not to be sustained upon examination based on the technical merits of the position. For the year ended July 31, 2024, the Company had no material unrecognized tax benefits, and based on the information currently available, no significant changes in unrecognized tax benefits are expected in the next 12 months.

The Company's policy is to recognize interest and penalties related to uncertain tax positions as income tax expense. The Company has no accruals for interest or penalties on its accompanying consolidated balance sheets as of July 31, 2024, and 2023, and has not recognized interest or penalties in the consolidated statements of operations for the years ended July 31, 2024, and 2023.

NOTE 12: RELATED PARTY TRANSACTIONS AND BALANCES

Parties are considered to be related if one party has the ability, directly or indirectly, to control the other party or exercise significant influence over the other party in making operating and financial decisions. This would include the Company's senior management, who are considered to be key management personnel by the Company. Parties are also related if they are subject to common control or significant influence. Related parties may be individuals or corporate entities. A transaction is considered to be a related party transaction when there is a transfer of resources or obligations between related parties.

a. The following related party salaries and directors' fees are included in the consolidated statements of operations and comprehensive loss:

	Year ended July 31,	
	2024	**2023**
Directors (*)	$ 534,861	$ 517,398
Officers (**)	2,075,492	1,881,171
	$ 2,610,353	$ 2,398,569

(*) Excludes the CEO who is a director

(**) Includes the CEO who is also a director

b. The following related party balances are included in the consolidated balance sheets:

	July 31,	
	2024	**2023**
Directors (*)	$ 153,852	$ 7,500
Officers (**)	319,478	33,253
	$ 473,330	$ 40,753

(Expressed in US Dollars, except share and per share data and unless otherwise indicated)

NOTE 13: FINANCIAL INCOME, NET

	Year ended July 31,	
	2024	**2023**
Interest income	$ 288,018	$ 891,213
Foreign exchange loss	(25,452)	(40,873)
Financial income, net	$ 262,566	$ 850,340

NOTE 14: BASIC AND DILUTED NET LOSS PER SHARE

Basic net loss per ordinary share is computed by dividing net loss for each reporting period by the weighted-average number of ordinary shares outstanding during each period. Diluted net loss per ordinary share is computed by dividing net loss for each reporting period by the weighted average number of ordinary shares outstanding during the period, plus dilutive potential ordinary shares considered outstanding during the period, in accordance with ASC No. 260-10 "Earnings Per Share". The Company experienced a loss in the year ended July 31, 2024 and 2023; hence all potentially dilutive ordinary shares were excluded due to their anti-dilutive effect.

	Year ended July 31,	
	2024	**2023**
Numerator:		
Net loss available to shareholders of ordinary shares	(4,931,548)	(20,302,394)
Denominator:		
Shares used in computing net loss per ordinary shares, basic and diluted	16,454,932	15,619,676

NOTE 15: SUBSEQUENT EVENTS

a. On August 7, 2024, the Company and BC Therapeutics amended the SPA, pursuant to which the Company could exercise the Second BC Therapeutics Option in traches of at least 20,000 shares of BC Therapeutics at $1.25 per BC Therapeutics Share.

   On August 7, 2024 and on September 23, 2024, the Company transferred $25,000 on each date and received a total of 40,000 shares. As of the date of this report the Company holds 460,000 shares in BC Therapeutics representing 56.1% of the total issued and outstanding shares of BC Therapeutics.

b. On August 7, 2024, 100,000 of the prefunded warrants issued in the May 2024 Offering were exercised into 100,000 common shares of the Company.

c. On September 12, 2024, the Company closed a registered direct offering for the purchase and sale of 12,325,000 common shares of the Company for aggregate gross proceeds of approximately $8.5 million before deducting placement agent fees and other offering expenses (the "September 2024 Offering"). In addition, the Company issued 616,250 placement agent warrants. The placement agent warrants have a term of five years commencing September 11, 2024, are exercisable commencing March 11, 2025, and have an exercise price of $0.8625 per common share.

d. On October 2, 2024, the Company closed a registered direct offering for the purchase and sale of 5,128,500 common shares of the Company and warrants to purchase up to an aggregate of 5,128,000 common shares of the Company for aggregate gross proceeds of approximately $5.0 million before deducting placement agent fees and other offering expenses (the "October 2024 Offering"). Each common share was sold together with one warrant to purchase one common share at a combined purchase price of $0.975. The warrants have an exercise price of $0.85 per share, and are immediately exercisable for a period of five years from grant date ("October 2024 Warramts"). In addition, the Company issued 256,425 placement agent warrants. The placement agent warrants are immediately exercisable for a period of five years from grant date at an exercise price of $1.21875.

e. As of the date of this report, 345,000 October 2024 warrants were exercised for gross proceeds of $293,250.