

BRIACELL THERAPEUTICS CORP.

FORM 8-K (Current report filing)

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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

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

Date of Report (Date of earliest event reported): October 1, 2024

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)

Commission File No. 001-40101

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered under Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

Item 8.01. Other Events.

On October 1, 2024, BriaCell Therapeutics Corp. (the “Company”) issued a press release to report dramatic anti-tumor response including complete resolution of temporal lobe breast cancer metastasis in a patient treated in the Phase 2 study of the Company’s Bria-IMT™ plus immune checkpoint inhibitor regimen. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 1, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

BRIACELL THERAPEUTICS CORP.

/s/ William V. Williams

William V. Williams
President and Chief Executive Officer

October 1, 2024



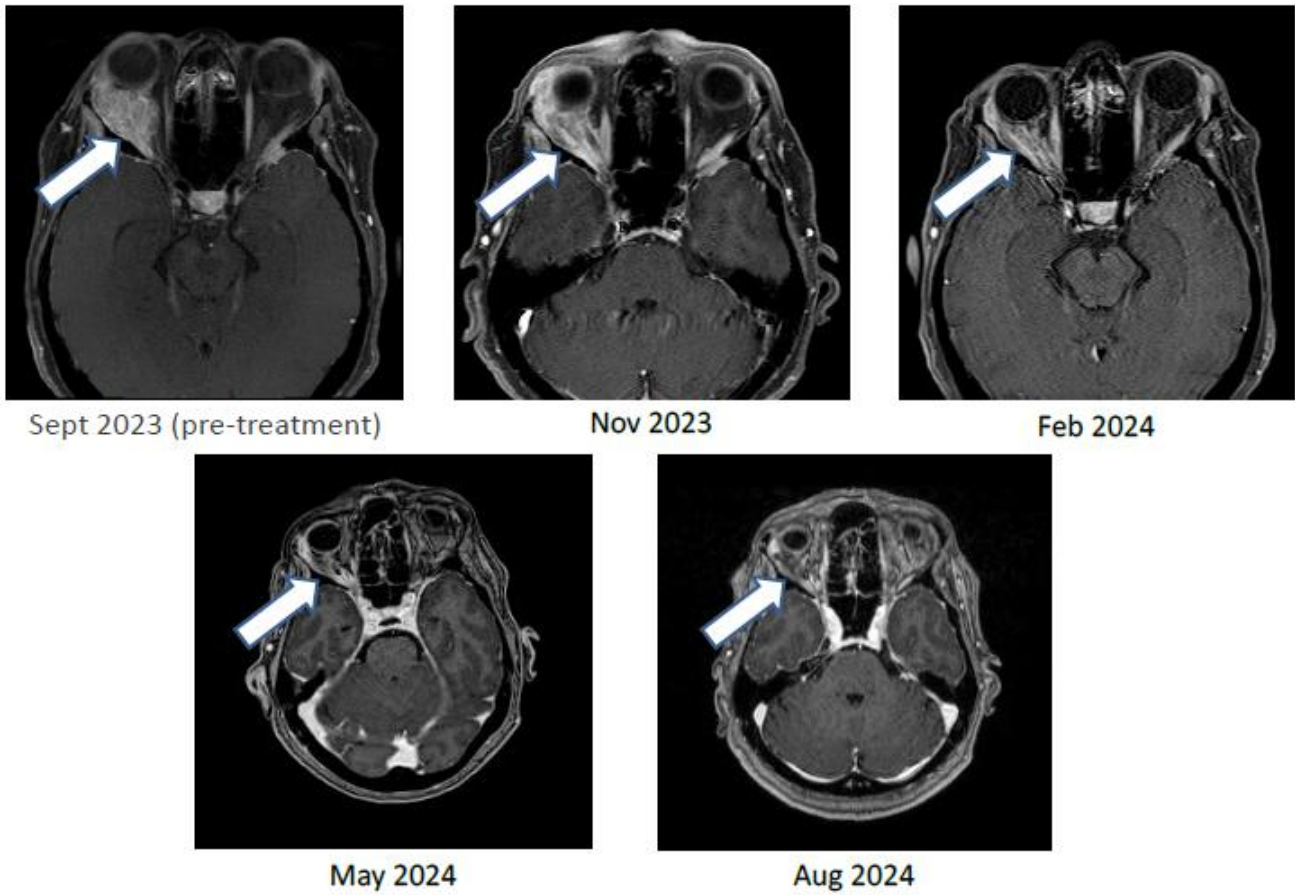
BriaCell Reports 100% Resolution of Brain Metastasis in Breast Cancer Patient with “Eye-Bulging” Tumor

- *Dramatic anti-tumor response includes 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 continues to receive BriaCell treatment*

PHILADELPHIA, PA and VANCOUVER, British Columbia, October 1, 2024— BriaCell Therapeutics Corp. (Nasdaq: BCTX, BCTXW) (TSX: BCT) (“BriaCell” or the “Company”), a clinical-stage biotechnology company that develops novel immunotherapies to transform cancer care, is pleased to report dramatic anti-tumor response including complete resolution of temporal lobe breast cancer metastasis in a patient treated in the Phase 2 study of BriaCell’s Bria-IMT™ plus an immune checkpoint inhibitor regimen. The patient demonstrated an initial partial response at 2 months in the brain lesion with no detectable disease following 8 and 11 months of treatment.

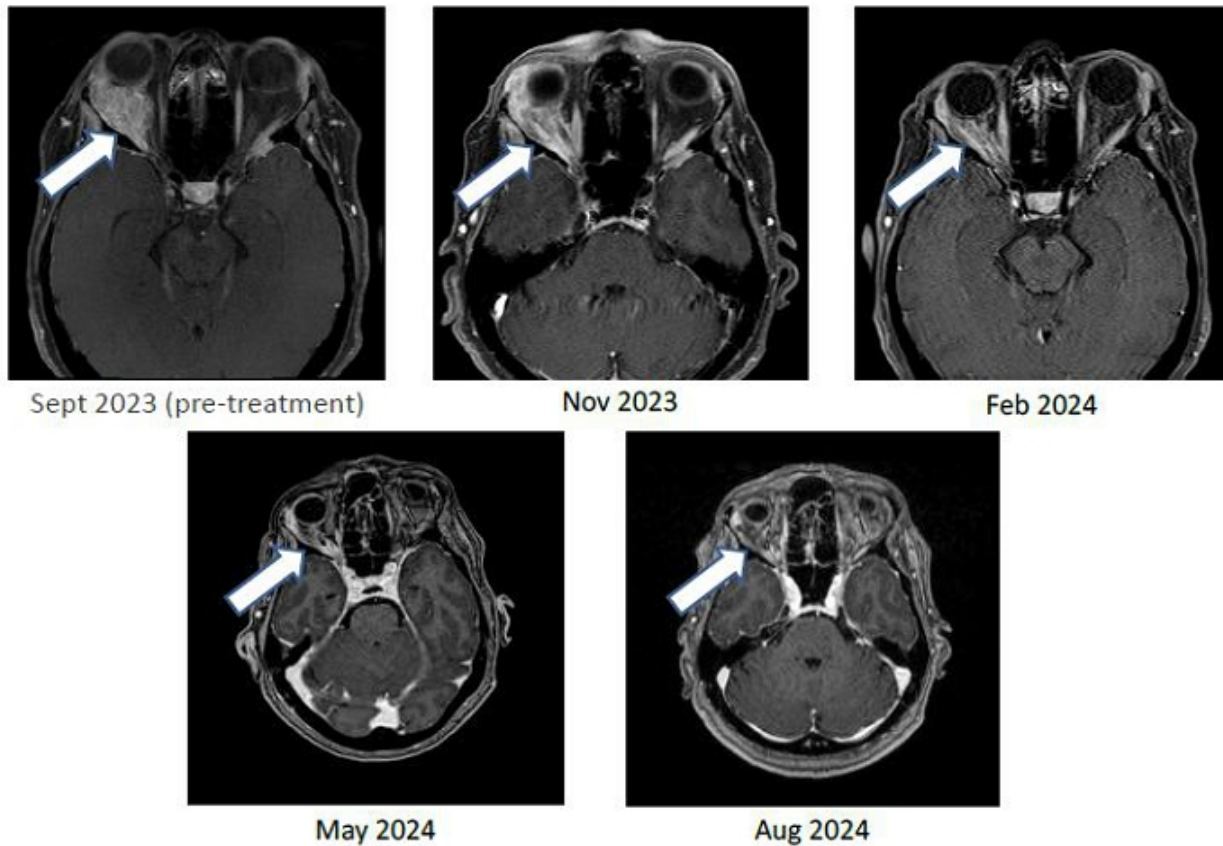
The heavily pre-treated patient who had failed 8 prior regimens including ADC therapy, previously demonstrated significant reduction of her “Eye-Bulging” orbital tumor and continues treatment with the Bria-IMT™ regimen. She has completed 17 cycles of treatment and has been on BriaCell’s Phase 2 study for 12 months. Also noteworthy is a sustained drop in her tumor markers, confirming the imaging results of marked tumor reduction.

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)



“Bria-IMT™’s potential therapeutic impact is unprecedented in metastatic breast cancer (MBC) in a brain metastasis setting. Our clinical findings, demonstrating significant tumor shrinkage in metastatic brain lesions, may transform the way we treat MBC patients with brain metastasis, and offers hope to cancer patients and their families fighting this devastating disease,” stated Dr. William V. Williams, BriaCell’s President and CEO. “These results support Bria-IMT™ as a potential new therapeutic option for MBC patients with brain metastasis. We look forward to evaluating the brain metastasis patient subgroup in our ongoing pivotal Phase 3 study in metastatic breast cancer.”

“We believe that the complete tumor resolution in this patient with brain metastasis, plus other cases of significant anti-cancer clinical responses in our Phase 2 MBC patients with brain metastasis, highlight the potential application of Bria-IMT™ in treating similar MBC patients,” commented Dr. Giuseppe Del Priore, BriaCell’s Chief Medical Officer. “The protracted time on therapy, now one year, attests to the excellent tolerability of the Bria-IMT™ regimen in combination with an immune checkpoint inhibitor which is being used in our pivotal Phase 3 study.”

About BriaCell Therapeutics Corp.

BriaCell is a clinical-stage biotechnology company that develops novel immunotherapies to transform cancer care. More information is available at <https://briacell.com/>.

Safe Harbor

This press release contains “forward-looking statements” that are subject to substantial risks and uncertainties. All statements, other than statements of historical fact, contained in this press release are forward-looking statements. Forward-looking statements contained in this press release may be identified by the use of words such as “anticipate,” “believe,” “contemplate,” “could,” “estimate,” “expect,” “intend,” “seek,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “target,” “aim,” “should,” “will,” “would,” or the negative of these words or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements, including those about BriaCell replicating positive data in its ongoing pivotal Phase 3 study; BriaCell’s Bria-IMT™ regimen bringing relief to cancer patients whose medical needs remain unmet; and the Bria-IMT™ regimen becoming a therapeutic option for metastatic breast cancer patients, are based on BriaCell’s current expectations and are subject to inherent uncertainties, risks, and assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate. These and other risks and uncertainties are described more fully under the heading “Risks and Uncertainties” in the Company’s most recent Management’s Discussion and Analysis, under the heading “Risk Factors” in the Company’s most recent Annual Information Form, and under “Risks and Uncertainties” in the Company’s other filings with the Canadian securities regulatory authorities and the U.S. Securities and Exchange Commission, all of which are available under the Company’s profiles on SEDAR+ at www.sedarplus.ca and on EDGAR at www.sec.gov. Forward-looking statements contained in this announcement are made as of this date, and BriaCell Therapeutics Corp. undertakes no duty to update such information except as required under applicable law.

Neither the Toronto Stock Exchange nor its Regulation Services Provider (as that term is defined in the policies of the Toronto Stock Exchange) accepts responsibility for the adequacy or accuracy of this release.

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