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NEWS RELEASE

IZOTROPIC ANNOUNCES REGULATORY APPROVAL PLANS TO LAUNCH IZOVIEW FOR BREAST CANCER DIAGNOSTICS IN PATIENTS WITH DENSE BREASTS IN THE U.S AND EU

VANCOUVER, BC, August 23, 2024 – **Izotropic Corporation** ("**Izotropic**" or the "**Company**") (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**), a medical device company commercializing IzoView, a breast CT (computed tomography) imaging system, is pleased to announce that it is pursuing a regulatory strategy in the U.S. and EU to launch IzoView as a diagnostic device indicated for use in patients with dense breast tissue, a normal variation associated with an increased risk for developing breast cancers.

The Company's reformed regulatory strategy positions IzoView Breast CT for market entry as a diagnostic imaging device to be used adjunctive to digital breast tomosynthesis ("**DBT**") and indicated for use in patients with dense breast tissue (BI-RADS C and D). This regulatory pathway in the U.S. will require a Pre-Market Authorization (PMA) clinical study with an estimated sample population size of 400 patients and an estimated cost of $3.5M USD. Izotropic is currently completing a pre-submission that it expects to complete and file with the U.S. FDA in approximately 6-8 weeks. Upon completing the pre-submission meeting with the FDA that will follow, the Company will make a further announcement regarding the full clinical study timeline, knowing in part that a period of 1-year post imaging of the last study patient will be required to validate negative breast cancer cases and prepare the final PMA submission for FDA approval.

The clinical study design intends to prove the superiority of DBT in combination with Contrast-Enhanced Breast CT compared to DBT images alone for the detection of breast cancers in a screening population of women with dense breasts. In the study, radiologists will read DBT and IzoView images together, complete a diagnosis using both images and compare the diagnostic accuracy against DBT images alone. By implementing an adjunct indication for use in IzoView's initial market launch strategy, Izotropic will be able to execute a smaller and less costly clinical study on a shorter timeline compared to other diagnostic regulatory pathways previously explored by the Company. This, in turn, expedites patient access to Breast CT technology for a population with an increased risk factor for developing breast cancer.

Given the risk factors of breast density and the severity of breast cancer diseases as a global concern, the Company is expanding its focus and will be applying for market approval in the EU under the CE Mark pathway. In the coming months, Izotropic will be engaging a designated organization known as a notified body that has the authority to assess the conformity of medical devices and other products under applicable EU legislation. The intended use, indication for use, and clinical burden needed for CE Marking for IzoView will be negotiated with the notified body under the new MDR process. Breast CT clinical data established in the U.S. will be leveraged in whole to support CE marking and may result in earlier commercialization in the EU before IzoView's market launch in the U.S. The schedule for CE Marking will be finalized after notified body negotiations.

What is Digital Breast Tomosynthesis?

DBT is a mammography-like compression-based breast imaging device that uses software to generate slightly 3D images from a series of images acquired in 2D. While mammography takes stationary images from the top and sides of the breast, the camera in DBT moves in an arc over the breast ranging from 15-50 degrees depending on the device model and reconstructs these images using software to provide more detail. DBT is replacing traditional 2D mammography for breast cancer screening because it has been shown to be more effective at breast cancer detection. However, the limited number of views collecting during the DBT imaging process means that the resulting images are not truly 3D.

With IzoView breast CT, the patient places their own breast in the IzoView imaging cup. There is no breast handling or potentially painful breast compression required. With a comfortable face down view, natural breast orientation is maintained, producing more suitable image outputs. The imaging hardware beneath the table then circles around the patient's breast, producing approximately 500 high-resolution images (depending on breast length) in approximately 10 seconds, with a radiation dose comparable to 2-view mammography. A true 3D reconstructed image (data set) is produced within 30 seconds, which a radiologist can then view from any angle like a 3D model, or slide through the 500+/- cross-sectional images individually to better determine tumor size, shape, location, and relation to internal breast structures.

As of August 2024, 8,915 certified facilities are operating under the Mammography Quality Standards Act in the U.S., and over 90% of these facilities have DBT units. Of the 26,045 accredited units at these facilities (mammography and DBT), DBT units account for 47% of these devices.

What is Dense Breast Tissue?

Breasts are comprised of three different types of tissue: fibrous and glandular tissues, which are both dense and fatty tissue. Breast density refers to the amount of fibrous and glandular tissue in the breast compared to fatty tissue. A grading system called BI-RADS (Breast Imaging Reporting and Data System) classifies breast density into four categories: (A) Almost entirely fatty breast tissue, found in about 10% of women; (B) Scattered areas of dense

glandular tissue and fibrous connective tissue, found in about 40% of women; (C) Heterogeneously dense breast tissue with many areas of glandular tissue and fibrous connective tissue, found in about 40% of women; and (D) Extremely dense breast tissue, found in about 10% of women. Izotropic's clinical study will focus on patients with BI-RADS C and D.

According to the National Cancer Institute, nearly half of all women in the U.S. aged 40 and older who get mammograms are found to have dense breasts. The denser the breast tissue is, the greater the risk factor for developing breast cancer. Dense breast tissue appears white on a mammogram- so do suspicious lesions and tumors. The density of the tissue itself and the compression required for mammography and DBT imaging could obscure abnormalities that may otherwise be further investigated if they were observed using these imaging modalities in patients with non-dense breast tissue. Currently, only mammography has been approved to diagnose and confirm breast density.

The Company's clinical study design incorporates breast density considerations consistent with the FDA's most recent position that, as of September 2024, it is mandated that all U.S. screening facilities inform women about their breast density with their mammography results. Some states additionally require a statement recommending women discuss the option of supplemental screening with ultrasound or MRI due to dense breasts with their primary care clinicians.

Izotropic's U.S. patent portfolio includes the only patent to measure breast density using the Breast CT modality.

FDA Filing History and Progress

Izotropic has been developing a relationship with the FDA since 2020 when its first pre-submission was filed with the intention of initiating a breast cancer-focused clinical study under a PMA pathway. This study was designed to demonstrate the superiority of non-contrast-enhanced breast CT over the current standard of care diagnostic imaging modalities- mammography, DBT, and ultrasound. After approximately two years of important filing work and communications with the FDA, the clinical study design was nearly completed. While nearing completion, the cost of executing the clinical study became three times higher than initially estimated before factoring in operating costs of at least $10+ million USD in pre-commercial regulatory investment, and the timeline became twice as long, which proved prohibitive. Although additional discussions and meetings were held with the FDA in an effort to reduce the timeline and number of patients required for the clinical study, and other indications for use without the use of contrast were discussed, this pathway became unrealistic given the Company's prior planning for clinical study costs of $3M USD plus an additional $2M to fund the build and install IzoView units at 2 study locations.

The clinical study details included the following:

Regulatory Pathway	Indication for Use	Study Population	Estimated Cost	Estimated Timeline
Class III PMA	Non-contrast enhanced diagnostic imaging for the detection of breast cancers with superiority over standard-of-care mammography, DBT and ultrasound	1,100+ women	$10M+ USD	5+ years

With an eroding market capitalization, it became challenging for the Company to secure the financial backing required to proceed with this clinical study for FDA approval as a Class III device. In early 2023, the Company re-engaged with the FDA in an effort to secure a downgraded Class II 510(k) clearance pathway with the intention of launching IzoView as a general breast CT imaging device adjunctive to mammography for broader investigational imaging versus a breast cancer-specific diagnostic device. This approach aimed to reduce submission expenses from tens of millions to just several hundred thousand dollars and to expedite from an approval timeline of 5+ years to a clearance pathway of approximately 6-9 months. This would be achieved by using pre-existing data from phantom Breast CT images and a small sampling of patient images instead of running a large clinical study. This approach proved to be unsuccessful. The FDA took the position that it did not consider imaging of the breast to be a general CT exam and that a clinical study was required. Although CT imaging devices are generally cleared through a 510(k) filing process and considered to be Class II devices by the FDA, the FDA ultimately advised that breast anatomy was considered separate and apart from other appendages and body parts and that they wanted anatomy specific imaging studies for specific indications for use and not a general CT device that images breasts. As a result, the Company has formally abandoned the 510(k) approach for initial market clearance.

The market clearance details included the following:

Regulatory Pathway	Indication for Use	Study Population	Estimated Cost	Estimated Timeline
Class II 510(k)	General/ discretionary use breast imaging without contrast adjunctive to mammography	Use of phantom images (non-human) from the pre-commercial model of IzoView and a small sampling of patient images	Under $1M USD	6-9 months

To circumvent this setback, Izotropic enlisted the expertise of 2 FDA specialists in April 2024: a regulatory expert with Class III PMA experience and a former FDA Director with the Division of Imaging, Diagnostics, and Software Reliability to review all historical FDA filings, formal responses, and communications to assist the Company in developing and implementing a regulatory and clinical strategy with an objective of achieving FDA market approval.

After considering several previously unexplored clinical study options, the Company met with the FDA on May 28, 2024, to discuss a revised intended use and clinical study design. This meeting was attended by the Company's FDA specialists and focused on obtaining a consensus from the FDA on the most appropriate regulatory path, intended indication for use, and clinical study design. As a result of this meeting and the additional necessary detailed planning that followed, Izotropic will be pursuing its initial market launch for IzoView as a contrast-enhanced diagnostic device adjunctive to DBT for patients with dense breast tissue.

The clinical study details include the following:

Regulatory Pathway	Indication for Use	Study Population	Estimated Cost	Estimated Timeline
Class III PMA	DBT in combination with Contrast-Enhanced Breast CT is superior to DBT alone for the detection of breast cancer in a screening population of women with dense breasts.	Estimated 400 women	Estimated $3.5M USD	To be announced after the pre-submission meeting. Expect a multi-year timeline to include a year post study period to the final PMA submission

CEO Message:

Mr. Robert Thast states, “Izotropic has invested considerable time and capital in the filing and regulatory preparation stages aimed at securing market approval or clearance for IzoView in the U.S. The current clinical study design selected for IzoView as a contrast-enhanced diagnostic device adjunctive to Digital Breast Tomosynthesis for patients with dense breast tissue is in line with the expectations of the FDA and supported by the new U.S. government-mandated breast density notifications for patients undergoing breast cancer screening. With a former FDA director advising the Company, we are now confident of the regulatory approach and approval pathways identified for U.S. and EU markets.

Once Izotropic has obtained formal acceptance from the FDA for its clinical study plan in response to the pre-submission, the Company will be in a position to confirm and finalize timelines and costs and endeavour to complete long-term debt funding tied to milestones or non-dilutive options to execute the clinical study and prepare for commercialization.

Ahead of a major financing, convertible debt and/or equity funding will be required for mandatory overhead; ongoing public company administrative line items; the lease, insurance, and basic expenses related to the Company's engineering facility in Sacramento, CA where the first pre-commercial IzoView device is situated; and for ongoing legal and patent related costs.

In lieu of major financing, Izotropic also has a significant opportunity whereby near-term debt and/or equity financing may be warranted to generate catalysts and improve its market capitalization by funding the build and installations of IzoView units in tier-one U.S. hospitals. The Company has always been mindful of the dilution associated with equity financing, and this operational culture will continue. Subject to debt and/or equity financing being amenable, the Company may proceed with this initiative to secure the partnerships required for the clinical study and place IzoView in the hands of researchers and physicians at world-renowned facilities for breast-related research. The research studies conducted on IzoView would produce data and journal publications that would drive regulatory approvals and clearances for future indications for use. This continuously evolving system with few limitations would drive progress and create long-term momentum for the Company and its shareholders.

While there are still challenges ahead as a development company, with capital being chief among them, Izotropic now has a defendable market authorization plan backed by esteemed FDA consultants that is optimal for both the Company and the regulatory authorities. With solidified plans and renewed energy, Izotropic is on its way to reinstating full operational activities to commercialize Breast CT for the more accurate diagnosis of breast cancers globally."

ON BEHALF OF THE BOARD

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About Izotropic

More information about Izotropic Corporation can be found on its website at izocorp.com and by reviewing its profile on SEDAR at sedar.com.

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