



Suite 424, 800-15355 24th Avenue,
Surrey BC V4A 2H9

1-833-IZOCORP | www.izocorp.com

IZOTROPIC ENGAGES DR. CRAIG ABBEY FOR BREAST CT READER STUDY DESIGN

VANCOUVER, BC –July 8, 2020– Izotropic Corporation (“Izotropic” or the “Company”) (CSE: IZO) (OTC US: IZOZF) (FSE: 1R3) is pleased to announce that it has engaged Dr. Craig Abbey, Ph.D., to develop and present proposed reader study designs to the FDA during the Company’s pre-submission meeting for approval of its Breast CT Imaging System.

Dr. Abbey has a Ph.D. in Applied Mathematics and currently holds a professional [Researcher](#) position at the University of California, Santa Barbara, where his interests include modeling human observer strategies for performing visual tasks in the presence of image noise and other degradations, and assessment of medical imaging devices and image processing in terms of performance in diagnostic and quantitative tasks.

A leader in his field, Dr. Abbey has served as a Scientific Reviewer for the FDA where he sat on independent review panels to evaluate reader studies proposed by companies seeking FDA approval of medical imaging devices. Notably, Dr. Abbey sat on the independent review panel for the approval of Hologic’s Digital Breast Tomosynthesis, and U-System’s Automated Breast Ultrasound System (ABUS).

In May of this year the Company engaged [FDA Consultant Dr. Anita Nosratieh, Ph.D.](#), to develop and manage the Company’s application for FDA approval. She spoke highly of the collaboration when she said *“Dr. Abbey is a world expert in designing clinical studies and the first name that comes to mind when I think of designing a reader study for an imaging device for the FDA approval process. He is an accomplished and brilliant mathematician and I am confident that his involvement with Izotropic will translate to expedited patient access to breast CT.”*

Dr. Abbey will be working closely with Dr. Nosratieh to complete and present the application to the FDA, which includes product and indication for use statements, device labelling terms and future marketing claims which will be substantiated by the clinical and validation studies.

Observer performance studies refer to methods of assessing the diagnostic accuracy of breast CT on the relevant cohort of patients. This will be accomplished in the form of a reader study where cases that are culled from breast-imaging clinics are imaged on both Breast CT and a comparison imaging modality, and these are interpreted by human readers (breast radiologists). The parameters and specifications of the studies are optimized through mathematical power calculation models.

By designing and presenting reader studies during the pre-submission meeting, the Company anticipates a more efficient study process and greater chances of adhering to timeline and budget estimates. Dr. Abbey elaborates: *“The likelihood of an approval without a lot of extra time spent is higher when you go through the pre-submission meeting and demonstrate to the FDA how the study addresses the goals of the regulatory approval process. When we execute in line with our pre-submission plan, with the expected outcomes, the likelihood of approval is high.”*

Dr. Abbey has also joined the Company’s growing [Advisory Board](#) and reflected on the Izotropic team and the reality of Breast CT FDA approval: *“I have the highest regard for Dr. John Boone and the team that has come from UC Davis. The clinical team is outstanding in their field and will continue to provide insight and guidance on how to best meet the needs of radiologists and their patients. This is a very capable group that has been put together and I’m ecstatic to be part of it and to contribute to moving this promising technology forward. It’s very exciting to see breast CT finally*



Suite 424, 800-15355 24th Avenue,
Surrey BC V4A 2H9

1-833-IZOCORP | www.izocorp.com

start to move towards demonstrated clinical efficacy and use on patients. To help patients, we must have a device that gets into breast imaging clinics and gets used. This is the mechanism for doing that when it comes to breast-cancer imaging.”

The Company is on track to submit its pre-submission application to the FDA in August of this year as initially reported on May 25th, 2020.

ON BEHALF OF THE BOARD

Robert Thast
Chief Executive Officer

About Izotropic Corp.

Izotropic Corporation and its wholly owned U.S. operating subsidiary, Izotropic Imaging Corp. have been established to commercialize the next generation of breast imaging technology for early diagnosis of breast cancer. The Izotropic Breast CT Imaging System produces high resolution breast images in 3D. A single 10 second breast CT scan acquires approximately 500 images, without painful breast compression, providing radiologists with fully 3D viewing of the scanned breast. Mammography scanning requires compression of the breast between 2 imaging plates, resulting in 2D images.

The Company has the exclusive worldwide license from the University of California, Davis (UC Davis) to commercialize the technology developed by principal founder and Company director Dr. John M. Boone and researchers at UC Davis. The license includes all intellectual property, trade secrets, patents and patent-pending applications that are the foundation of the Company’s breast CT imaging platform.

Approximately \$20 million in research funding and over 15 years of research and development have been invested in developing this groundbreaking breast CT imaging technology. Research includes a current, ongoing \$2.9M U.S. clinical trial at UC Davis Medical Center.

The Company founders believe that this technology will be a disruptive entry to the market, overcoming many of the challenges faced by existing breast imaging modalities.

Phone: 1-833-IZOCORP
Email: info@izocorp.com
Website: izocorp.com