



info@izocorp.com www.izocorp.com  
#424, 800-15355 24<sup>th</sup> Ave. Surrey, BC V4A 2H9

## NEWS RELEASE

### IZOTROPIC UPDATES TIMELINES FOR CLINICAL STUDY AND FABRICATION OF INITIAL IZOVIEW UNITS

**VANCOUVER, BC – June 3, 2021 – Izotropic Corporation (“Izotropic” or the “Company”)** (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**) a Company commercializing “Izoview”, a true 3D, dedicated Breast Computed Tomography (CT) imaging technology for the diagnostic identification of breast cancers, provides updates on the following:

- Izoview, 5<sup>th</sup> generation, enhanced product design for performance improvements, added usability, increasing competitive advantages and target market
- Clinical study and regulatory pathway for regulatory authorization and market preparation process
- Product and clinical development milestones for the initial Izoview device

Izotropic announced today it has completed a comprehensive review of its R&D strategy to yield a differentiated offering for the Company’s priority markets, while positioning the business for continual innovation and disruptive breakthroughs. A combination of Covid-19 related delays and discussions with key suppliers of primary components for the Izoview system led the Company to revise its original commercialization efforts, which has resulted in a more robust device design and capability. This will align the Company’s core functions and commercial solutions for optimization across target customer needs as the competitive landscape evolves over time.

#### **Izoview: 5<sup>th</sup> Generation Product and Target Market**

The Company’s original strategy was to closely mirror the 4<sup>th</sup> generation Breast CT device now under clinical investigation at UC Davis for the Company’s FDA study and finalize user and patient handling requirements. As Covid-19 set in, the Company began to factor in the evolving dynamics, the impacts on supply chains, and the associated challenges of running a clinical study during a pandemic. At the same time, next-generation primary components became available and the Company therefore decided to adjust the business plan to its benefit. As a result, now going into the initial clinical study comparing Izoview with diagnostic

mammography, Izotropic expects to deliver a better performing system, with a subsequent broader product offering and a more competitively priced Breast CT system.

More than U.S. \$25M has been invested across all aspects of the breast CT system, with the majority of this capital on R&D and clinical studies at UC Davis Medical Center, funded primarily by the National Institutes of Health in the U.S. Over the past 2 years Izotropic has made specific investments related to engineering capabilities, onboarding personnel, and investigating and finalizing the Izoview platform strategy. The Company has also advanced its technical planning and documentation, sourced and purchased critical components, implemented a quality management system, which is all necessary to make Izoview a high-performing device for mass use.

Capital expenditures of late have resulted in internal and external engineering teams establishing platform functionality and confirming that upgrade and testing plans will be optimal for the breast imaging environment and compliant within relevant regulatory jurisdictions.

In addition, the Company continues to invest in future activities associated with our initial clinical study and product launch, including logistics planning, and engagement with potential collaborators, insurance payors, hospitals, clinics, and patients.

The 4<sup>th</sup> generation prototype at UC Davis was built and tested by founder and director Professor John M. Boone Ph.D. and is currently being used in a university hospital setting for academic and clinical research purposes. The significance of upgrades to improve performance is demonstrated by data published comparing 4<sup>th</sup> generation breast CT image performance against its predecessors. The latest model at UC Davis was built using state-of-the-art technology of its day that enabled over three times higher resolution compared to the initial prototype (Gazi et al. 2015). In addition to hardware improvements, Izotropic is developing new image reconstruction software utilizing the latest machine learning algorithms to deliver both high resolution and low noise images at low radiation dose levels. Aside from improved detection capabilities, Izotropic anticipates higher resolution 3D images could provide more accurate margin analysis (viewing edges of a tumor), lesion characterization (determining the qualities of an abnormality for accurate diagnosis), and higher spatial resolution (the imaging ability to differentiate between internal breast structures) (Aminololama-Shakeri et al. 2016). The Company intends to investigate these aspects in follow-on clinical studies after initial market authorization.

The initial target market for Izoview is in the U.S. and consists of over 8,500 hospitals and diagnostic imaging clinics that may benefit from having one or more Breast CT imaging units (GlobalData 2019).

When considering market positioning, 3D breast imaging is currently conducted mainly with costly and time-consuming MRI. Izoview's dedicated 3D breast imaging system shields the

rest of the body from radiation and acquires images in approximately 10 seconds. Izotropic intends to price the Izoview system at less than half the price of whole-body MRI.

Izotropic's revenue streams will include capital equipment sales, lease payments, or pay-per-use, providing customers with options which meet their unique needs. Additional revenue items will include maintenance contracts, sterile disposables, software feature upgrades, and additional hardware modules.

### **Clinical Study and Regulatory Pathway**

Initial market launch is planned for the U.S. with other jurisdictions to follow. The U.S. FDA requires a Pre-Market Approval (PMA) with the Company's proposed clinical study design being developed by Izotropic Advisor Dr. Craig Abbey, who has served on breast imaging device Scientific Review Panels for the FDA. The purpose of the clinical study is to demonstrate superior performance of diagnostic breast CT imaging over diagnostic mammography procedures. The overall study will take an estimated 18-24 months which includes the requirement for 12-month follow-up to confirm that diagnosed negative cases remain negative. During the negative case validation period, Izotropic will be focused on building customer interest, expediting additional platform applications, testing modules and accessories, and initiating new clinical studies for additional indications of use within the Breast CT platform.

"We're setting up to increase customer appeal with more add-ons and building in additional revenue streams. Izotropic plans to offer solutions across the gamut of breast health care, including screening and diagnosis in radiology, treatment planning and monitoring in surgical oncology, and breast reconstruction and implant monitoring in plastic and reconstruction surgery", said CEO Dr. John McGraw.

Izotropic is collecting and incorporating feedback to finalize the clinical study design through its partnership with Excite International, a global network of insurance payors, health systems, clinician scientists, and end-users. This process is designed to increase speed of global adoption upon regulatory approval. Details of the initial clinical study and study partners will be issued in a press release prior to the commencement of the study.

### **Product and Clinical Development Timelines for Izoview**

Due to the Covid-19 pandemic and the material adjustments to the initial business plan, the Company's timeline projections for clinical development have changed. Anticipated milestones are now as follows:

## **Anticipated Milestones**

### Q3 2021

- 3D imaging reconstruction software implementation begins
- Mechanical and electrical design completed
- Clinical trial design finalized

### Q4 2021

- Completion of industrial design
- Izoview fabrication begins and initial device build
- Clinical trial site selection

### Q1 2022

- Reconstruction software pipeline complete
- Medical device certification including electrical, radiation, and mechanical
- First device with demonstration of image quality on a phantom

### Q2 2022

- First human breast imaging on Izoview
- Clinical trial device units begin production and first Izoview unit is shipped to begin clinical study

### Q3 2022

- Module building and testing for additional products
- Customer interest initiatives
- Design second clinical study

Dr. John McGraw commented, "To recap, when I joined Izotropic the initial business plan was to essentially duplicate the current Breast CT model with minor upgrades and submit one Izoview unit in a small clinical study to fast-track market approval. Although Covid-19 limited progress and the ability to expedite our plans, recent advancements, new opportunities, and collaborations have materialized to enhance the Izoview system and expand our product pipeline for the future. There are a greater number of applications for Izoview than initially envisioned. While the primary focus is obtaining market authorization and commercializing Breast CT as a diagnostic imaging device, the revised business plan now is to explore and provide solutions and applications across women's breast health and I am committed on every level to execute on this aggressive plan."

**ON BEHALF OF THE COMPANY**

### **For investor relations inquiries, contact:**

James Berard

Email: [jberard@izocorp.com](mailto:jberard@izocorp.com)

Cell: 778-228-2314

Toll Free: 1-833-IZOCORP ext.1

### **References**

Aminololama-Shakeri S, Hargreaves JB, Boone JM, Lindfors KK (2016) Dedicated Breast CT: Screening Technique of the Future. *Curr Breast Cancer Reports* 8:242-247. <https://doi.org/10.1007/s12609-016-0227-2>

Gazi PM, Yang K, Burkett GW, et al (2015) Evolution of spatial resolution in breast CT at UC Davis. *Med Phys* 42:1973-1981. <https://doi.org/10.1118/1.4915079>

### **Forward-Looking Statements**

This document may contain statements that are "Forward-Looking Statements," which are based upon the current estimates, assumptions, projections and expectations of the Company's management, business, and its knowledge of the relevant market and economic environment in which it operates. The Company has tried, where possible, to identify such information and statements by using words such as "anticipate," "believe," "envision," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," "contemplate" and other similar expressions and derivations thereof in connection with any discussion of future events, trends or prospects or future operating or financial performance, although not all forward-looking statements contain these identifying words. These statements are not guarantees of performance and involve risks and uncertainties that are difficult to control or predict, and as such, they may cause future results of the Company's activity to differ significantly from the content and implications of such statements. Forward-Looking Statements are pertinent only as of the date on which they are made, and the Company undertakes no obligation to update or revise any Forward-Looking Statements to reflect new information or the occurrence of future events or circumstances unless otherwise required to do so by law. Neither the Company nor its shareholders, officers, and consultants, shall be liable for any action and the results of any action taken by any person based on the information contained herein, including without limitation the purchase or sale of Company securities. Nothing in this document should be deemed to be medical or other advice of any kind.