



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

NEWS RELEASE

IZOTROPIC PROVIDES REGULATORY AND OPERATIONAL UPDATES

VANCOUVER, BC, January 8, 2024 – **Izotropic Corporation** (“**Izotropic**” or the “**Company**”) (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**), a medical device company commercializing IzoView, a CT (computed tomography) imaging system, that produces images of anatomy for non-invasive characterization of tissue with an application in breast imaging, provides an update on its regulatory status with the U.S. Food and Drug Administration (“**FDA**”) and operational activities.

FDA Regulatory Update

Izotropic completed a pre-submission meeting with the FDA on October 25, 2023. The purpose and objective of this meeting were to facilitate a productive dialogue, obtain valuable feedback, and confirm the next steps in the Company's regulatory strategy for market entry, which focuses on broadening IzoView's intended use as a CT tool with market clearance as a Class II device under the FDA's 510(k) pathway.

Prior to the October meeting, the Company had held other pre-submission meetings with the FDA regarding a Class III diagnostic indication for use comparing IzoView to standard-of-care imaging modalities through a Pre-Market Approval regulatory pathway. The Class II 510(k) pre-submission was filed as a continuation of the pre-existing Class III PMA file at the FDA, and as such, the meeting took place with the FDA's Mammogram and Ultrasound team, and the FDA's CT team members were not present. The discussions allowed the Company to clarify its revised regulatory strategy to the FDA, and an announcement followed disclosing that while further discussion with the agency regarding the details of this regulatory strategy will be required to ensure its viability, the FDA appeared open to the Company's new market clearance direction.

As required by the FDA for purposes of concurrence, Izotropic promptly coordinated with its team members to draft and finalize meeting minutes, which were submitted to the FDA for review. Izotropic received a formal acknowledgment letter on November 8, 2023, from which the FDA had a 30-day period to review the meeting minutes and respond. On December 7,

2023, Izotropic received the minutes back from the FDA, and the material information discussed in the meeting was consistent for both the FDA and Izotropic, and the meeting minutes were subsequently approved.

Since the meeting, Izotropic has maintained an ongoing correspondence with the FDA via email regarding ongoing questions and responses to the pre-submission meeting content and has received confirmation that the pre-submission material has been provided to the FDA CT team; the FDA representatives that attended the October 2023 meeting have met with the CT team to discuss the pre-submission content; and the FDA has agreed to provide a response with more definitive guidance to the Company in January 2024.

For clarity to Izotropic's shareholders, as of the date of this news announcement, there has been no material change to the Company's regulatory plans and no definitive decision provided by the FDA. Izotropic will promptly report the outcomes of the FDA's response once it becomes available.

Operations and Business Development Update

Izotropic's ongoing corporate activities and management's focus, in addition to FDA regulatory efforts, are described below:

The Company has been in advanced discussions regarding IzoView device placement and specific clinical studies at a tier-one U.S. healthcare provider facility and is working with them to conclude a definitive agreement.

Business-related discussions continue with a medium-sized healthcare industry entity regarding a global marketing arrangement, sub-licensing opportunities, new product development, manufacturing of specific IzoView applications, and with a NASDAQ-listed healthcare company regarding a potential merger. Concluding these negotiations and finalizing agreements are subject to a definitive regulatory pathway and timing for market clearance from the FDA. In addition to normal course funding, Izotropic is pursuing non-dilutive upfront capital as a condition of closing on any potential sub-licensing agreement, and it will continue to seek non-dilutive capital in negotiations where feasible.

On the advice of Izotropic's regulatory advisors and legal counsel, the Company continues to defer making any claims pertaining to the exact indications for use for IzoView until a regulatory path is confirmed. In following this advice, the Company plans to reinstate awareness efforts when the required information to clearly articulate the near-term value proposition is available and complete, and Izotropic is not at risk of making claims that may affect its Class II 510(k) regulatory strategy in its awareness efforts and activities.

In anticipation of definitive guidance from the FDA, management has been working on updating its business plans and developing materials for an updated vision for the IzoView platform within an Innovation Ecosystem with multiple devices for unique clinical applications that harness the power of ultra-high-resolution cone-beam CT technology. These applications are based on existing and patent-pending intellectual property, potential uses identified in published papers from UC Davis Medical Center from which Izotropic has the exclusive global rights to IzoView's technology, and the potential future integration of artificial intelligence, machine learning, augmented and virtual realities, and nanotechnologies. Supporting materials in the form of charts and infographics are being developed to display this information in a simple visual format and are intended to be used in the Company's corporate materials and on social media platforms when the Company is ready to execute a clear plan and able to relaunch its awareness initiatives.

The Company thanks its executives, management, technical team, and board members who have forgone compensation in 2023, demonstrating their belief in Izotropic's technologies and future. Current resources have been prioritized towards FDA regulatory efforts and essential administrative items, including maintaining the Company's engineering facility in Sacramento, California, and required insurance; patent filings; and matters relating to public company compliance such as listing and filing fees, accounting and audit-related fees, and fees associated with legal requirements.

Upon securing funding, management intends to align resources with endeavors directly linked to activities and milestones that enable market clearance and IzoView device sales.

Izotropic acknowledges and appreciates the patience exhibited by its shareholders as it works to implement and execute objectives in 2024.

ON BEHALF OF THE BOARD

Mr. Robert Thast, CEO

Cell: 604-220-5031

Contact:

Email: info@izocorp.com

Toll Free: 1-833-IZOCORP ext.1

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.

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, including those related to capital requirements 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. All images are for illustrative purposes only. IzoView has not yet been approved or cleared for sale.