January 29, 2025

Izotropic Announces Timelines and Milestones to IzoView Product Launch

- Unique dense breast tissue focus to drive expedited recruitment rates; modular clinical study design reduces time to PMA submission by ~6 months -

- 3 Site U.S.-based clinical study enables early data collection to kickstart European CE Mark Application -

- Company to announce development of 2 new medical imaging devices in the next 12 months to trigger momentum and increase valuation during clinical data collection phase -

VANCOUVER and SACRAMENTO, January 29, 2025, Izotropic Corporation (CSE: **IZO**) (OTCQB: **IZOZF**) (FSE: **1R3**) ("**Izotropic**" or the "**Company**"), a medical device company commercializing imaging-based products utilizing innovative and emerging technologies for the more accurate screening, diagnoses, and treatment of breast cancers, is pleased to provide timeline and milestone details for its forthcoming clinical study for FDA approval of its first medical imaging device, the IzoView Breast CT Imaging System ("**IzoView**"), with contrast-enhancement for breast cancer screening adjunctive to digital breast tomosynthesis ("**DBT**") commonly referred to as 3D mammography for patients with dense breast tissue.

The timeline to IzoView product launch is segmented into 7 phases, each containing key, value-add milestones that represent significant catalysts: Prepare IzoView, Site Setup, Clinical Study, Reader Study, Modular Submissions, PMA Application, and Approval and Sales. The phases contain overlapping elements that are visualized in the accompanying Figures either below or attached to this press release.

The following information contains forward-looking estimates that are based on current projections and are subject to change. The starting date of the timeline is dependent on financing, which may be completed in whole or in part. The reference date ranges provided are not guaranteed and may be adjusted due to financial opportunities and/or limitations, regulatory reviews, study results, or unforeseen circumstances. Please refer to ongoing official updates for the most accurate information.

1. **Prepare IzoView**

The device preparation phase encompasses all events post-financing to shipping 3 IzoView units from the Company's engineering facility in Sacramento, California to 3 participating

clinical study sites in the U.S. The first model of IzoView is fully engineered and requires completion of its previously initiated User Interface Software, followed by Characterization and Optimization of the software with the device using an imaging phantom (an object as a stand-in breast) to calibrate the machine. Milestones then include completion of a third-party radiation survey certification to document safe radiation levels pursuant to IzoView's unique self-shielding design, whereby it can be operated in any room without the requirement of leaded walls and shielding particians as seen with other radiation emitting medical imaging devices. IzoView previously passed a Canadian-based radiation survey prior to the establishment of its U.S. facility. Quality controls and a series of additional standard commissioning and regulatory tests are then required prior to shipping IzoView Unit #1 for installation and testing at the first clinical study site. A 6-month period is anticipated from project initiation to the shipping of the first unit, followed by 2 back-to-back 6-week periods for the building, testing, and shipping of IzoView Units #2 and #3 to the remaining 2 clinical study sites.

This phase includes significant accelerators and news flow as milestones are achieved and includes releases of new IzoView device images and photos.

2. Site Setup

Site setup covers all activities from sites receiving their IzoView Units to bringing each location to a state of readiness to image their first patients. This phase initiates while IzoView Unit #1 is being completed and will involve formal contracting and approvals with each clinical study site, engagement of a clinical research organization ("**CRO**") who will manage the overall study (ensuring uniform processes and procedures at each site to mitigate exclusion and maintain data integrity), and the hiring of on-site clinical coordinators.

The sites will receive IzoView Units in individual physical modules that can be walked onto standard-sized elevators and through standard-sized doorways, unlike other medical and breast imaging devices that can require the removal of buildings' walls, cranes, and road closures for installation. The IzoView commercial model has been designed and engineered in a modular sub-system format, meaning each of the device's subsystems can be packaged and shipped easily, owing to the Company's distinct engineering approach that prioritized efficiency, manufacturability, and ease of future maintenance and repairs. After installations, the units will be tested, and on-site staff will be trained in IzoView's operations. The projected timeline for site setup at the first clinical study site is a projected 5-month period, followed by successive IzoView installations at the second and third sites upon completion of IzoView units. The contracting and approval processes with clinical study sites are a planned priority, and their timelines are expected to overlap.

This phase forecasts ongoing news flow, with the announcements of study site partners, on-site testing approvals, and image releases of IzoView on location as pivotal drivers.

3. Clinical Study

The Clinical Study phase is where the clinical data is collected and consists of recruiting patients, imaging patients on IzoView, and follow-up imaging. The statistical work included in the Company's pre-submission to the U.S. FDA anticipates a 9-18 month period to recruit and image the number of women required followed by a 12-month negative case validation period

to ensure that the patients diagnosed breast cancer-free during the clinical study remain that way one year later for an accurate diagnoses. The range in length of time to recruit and image women in the study can be impacted by factors including the motivation of the clinical study site and its volume of patients, effective advertising by the CRO, the experience of the clinical coordinators, and the motivation of the patients presented with the opportunity to participate. Given that patients are to be compensated for their participation in the Company's clinical study (per the industry standard), and the increasing awareness of the inadequacies of current standard-of-care imaging modalities per the FDA and U.S. Preventative Task Force for patients with dense breast tissue, the Company's outlook for its target recruitment rates is optimistic.

Noteworthy events during this period related to the U.S.-based study include the first and last patients imaged at each clinical study site and the beginning and end of the negative case validation period.

During the Clinical Study phase, the Company intends to take a portion of the patient imaging data collected to support an application for a CE Mark in Europe. In preparation for this application, 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 MDR process. Details of the timelines for European market authorization are to be announced prior to the application.

4. Reader Study

The Reader Study phase focuses on the preparation and completion of the multi-reader multi-case ("**MRMC**") study, where Radiologists read and score the images taken during the clinical data collection phase. Prior to the actual Reader Study, the Company with its CRO will develop, test, and finalize training methods that will be used to train the Radiologists during the MRMC study to properly interpret IzoView Breast CT images and define their confidence levels in their diagnoses in a uniform measurement scale.

Advance recruitment of Radiologists is projected to take place over a 6–9-month period, in tandem with the Clinical Study phase. After the full Clinical Study Phase is complete, a set of participating Radiologists will mark the locations of lesions and tumors on the breast images (known as truthing), and another set of Radiologists will read the images, mark the locations of abnormalities and score their confidence level in their diagnosis over a projected 3-month period.

The Reader Study phase supports news flow with important value-add momentum builders in the form of milestones related to processing imaging data and exposing the power of IzoView Breast CT images directly to hands-on experienced Radiologists.

5. Modular Submissions

The Company's FDA regulatory pathway requires a PMA (Pre-Market Approval) submission to the agency to approve IzoView for sale in the U.S. The Company is currently waiting for a pre-submission meeting date to be provided by the FDA. For the purposes of maintaining efficiency

for both the Company and the FDA, the Company has opted to submit its PMA in 4 separate modules: Verification, Non-Clinical Validation, Manufacturing, and Clinical Data. The first 3 modules can be successively drafted and submitted to the FDA during the 12-month negative case validation period of the Clinical Study phase. By moving these modules up on the timeline, the Company expects to save ~6 months, and an opportunity is created for a reduction in the FDA's processing time of the PMA application, further enabling IzoView sales and revenue sooner.

6. Submit PMA Application

The PMA application phase describes all activities related to processing and analyzing the data from the Reader Study and formatting the results into the final Clinical Data module for submission to the FDA for approval of IzoView.

The Company's Biostatistical Consultant who led the development of the clinical study design alongside Izotropic's lead FDA Consultant will be responsible for the data analysis.

This phase aids news flow efforts with milestones required for the final submission of the PMA, which represents a significant event of profound importance, as it is the last step before obtaining regulatory authorization in the U.S. Once received, the Company can take orders and proceed with mass manufacturing of IzoView Breast CT.

7. Approval and Sales

With IzoView approved for use in the U.S., Izotropic can formally launch IzoView and sell units at a discounted rate to its clinical study sites (as is customary) so they can begin advertising IzoView commercially and image their patients. The Company can re-engage with its database of prospective buyers that it has been accumulating since inception, and begin a nationwide marketing campaign for IzoView with traditional methods and through the advocacy of its well-respected scientific team members and members of its Advisory Board.

In continuing Izotropic's mission to change the breast cancer industry and provide better outcomes for those affected by breast cancer, Izotropic will announce the development of 2 new breast-dedicated medical imaging-based devices within the next 12 months, and the development of an IzoView accessory after IzoView has been approved for sale.

The development of new devices is intended to propel value and drive growth and has been strategically timed to ramp up during the less active Clinical Study phase of the IzoView timeline to market launch. This approach allows Izotropic to continue with its primary goal of bringing IzoView to market while engaging with its team at large, maximizing business potential, and utilizing value-generating resources available to the Company.

The expansion of the IzoView product portfolio provides the opportunity to maintain steady news flow with reports on new technologies and engineering breakthroughs, research and development accomplishments, new intellectual property rights, patent prosecutions, testing and certifications, and the formation of new strategic alliances.

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

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.

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STEPS TO APPROVAL

PREPARE IZOVIEW	UI Software, Characterization & Optimization with Phantom, Radiation Survey, Quality Controls, 3rd Party Certifications, Ship Unit #1, Prepare and Ship IzoView Units #2 and #3
SITE SETUP	Site Contracting, Engage CRO, Clinical Coordinators, Approvals and Setup, IzoView Installations, Training and Testing
CLINICAL STUDY	Patient Enrollment, First Patient Imaged, Early Data for CE Mark Application, Last Patient Imaged, Negative Cancer Case Validation Period
READER STUDY	Radiologist Recruitment; Development and Testing of Training Methods; On-site Training, Truthing, and Scoring
MODULAR SUBMISSIONS	Submissions of Verification Module, Non-Clinical Validation Module, and Manufacturing Module during Negative Cancer Case Validation Period
SUBMIT PMA APPLICATION	Write Program to Process Data for Analysis, Analysis of Clinical Data, Draft Clinical Data Module, Submit Final PMA to the FDA for Approval
APPROVAL & SALES	IzoView Approved for Use, First Sales to Clinical Study Sites, First Orders

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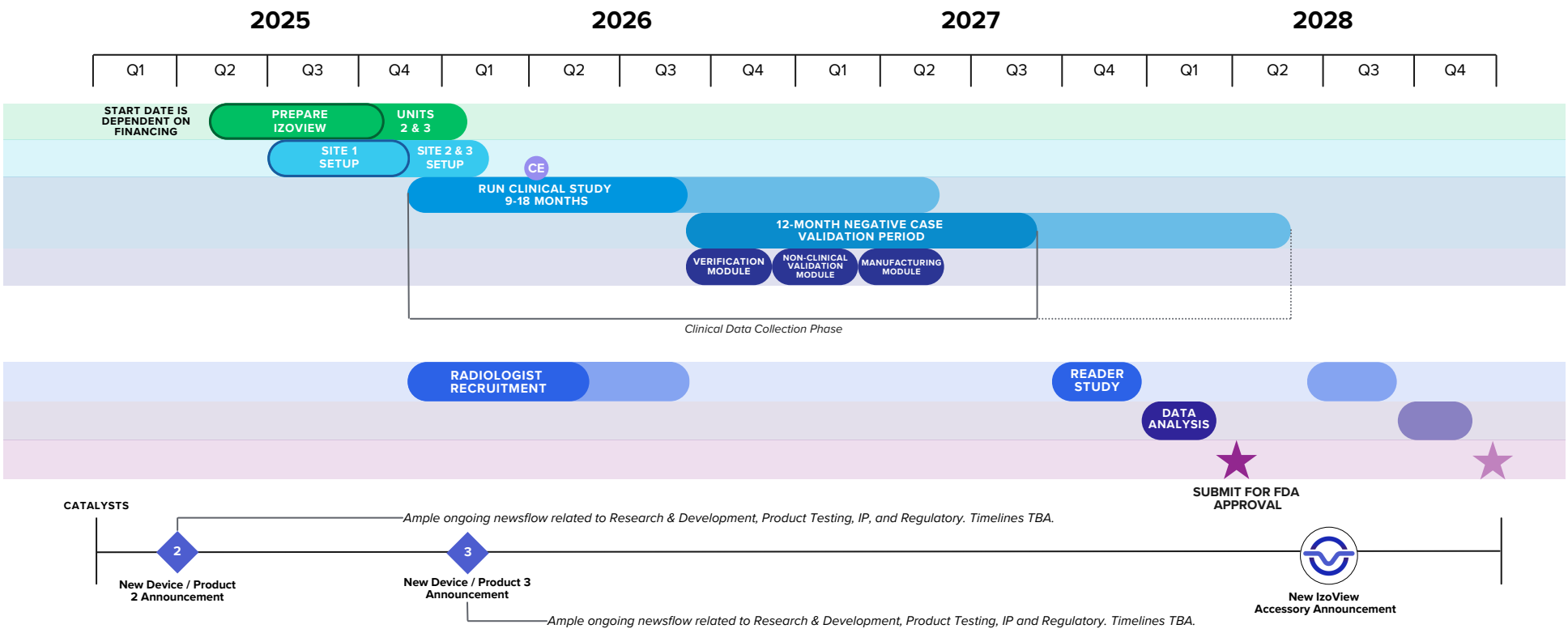
FDA TIMELINE & MILESTONES



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