

**IZOTROPIC CORPORATION**

**Annual Information Form  
For the year ended April 30, 2022**

**Prepared as of: November 3, 2022**

**IZOTROPIC CORPORATION**  
**2022 Annual Information Form**  
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# IZOTROPIC CORPORATION

## 2022 Annual Information Form

### PART 1 INFORMATION ABOUT CONTENT IN THIS DOCUMENT

#### 1.1 Date of Information

All information contained in this Annual Information Form (“AIF”) is as of November 3, 2022, unless otherwise indicated. As used in this AIF and unless otherwise indicated, the terms “we”, “us”, “our”, “Company”, and “Izotropic” refer to Izotropic Corporation and its direct and indirect subsidiary as set out in Section 3.2.

#### 1.2 Currency

The reporting currency of the Company is the Canadian dollar and all financial information presented in this AIF is in Canadian dollars, unless otherwise indicated.

#### 1.3 Cautionary Note Regarding Forward-Looking Information

Izotropic cautions readers regarding forward-looking statements found in this document and in any other statement made by, or on the behalf of the Company. Statements contained in this AIF that are not historical facts are “forward-looking information” or “forward-looking statements” (collectively, “**Forward-Looking Information**”) within the meaning of applicable Canadian securities laws.

Forward-Looking Information includes, but is not limited to, the Company’s ability to obtain necessary government and regulatory approvals, including FDA market approval; the Company’s ability to successfully complete the design and development of the Commercial Unit (as defined herein); the Company’s ability to successfully commercialize IzoView; the Company’s ability to protect the intellectual property granted to the Company under the License Agreement (as defined herein); the success of the Company’s sales and marketing efforts; the Company’s ability to maintain its competitive advantages; new developments in the area of cancer detections and the efficacy of competing technologies; market acceptance of the Company’s products and services; the Company’s ability to raise additional capital as and when needed and on acceptable terms; the effect of the COVID -19 pandemic on R&D teams, manufacturing, supply chain, clinical study operations and recruitment ability of clinical study sites, cancer positivity rates at each sites, as well as statements with respect to management’s beliefs, plans, estimates, and intentions, and similar statements concerning anticipated future events, results, circumstances, performance or expectations that are not historical facts; the Company’s lack of production history; risks related to the Company’s ability to satisfy the terms of the License Agreement and maintain the License in good standing; risks related to the Company’s ability to complete the design and development of the Commercial Unit, as well as create a physical prototype of the Commercial Unit; risks related to the Company’s ability to timely obtain regulatory approvals, including FDA approval, in order to satisfy the terms of the License Agreement; risks related to the Company’s ability to obtain additional required capital; risks related to the Company’s ability to timely enter into leasing agreements with hospitals and clinics to lease IzoView; increased competition that adversely affects business, estimations about the size of the target market; risks related to laws and regulations affecting government benefit programs could impose new obligations on the Company, require it to change its business practices, and restrict its operations in the future; risks related to the international nature of the Company’s business including: fluctuations in currency exchange rates, multiple legal and regulatory requirements that are subject to change and that could restrict the Company’s ability to manufacture, market, and sell its products, trade-protection measures and import or export licensing requirements, difficulty in establishing staffing and managing operations, differing labour regulations, inflation, recession, and fluctuations in interest rates, political and economic instability and price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization, and other governmental action; risks inherent to the Company’s industry with respect to technological change; risks related to management of the Company’s growth; risks related to protection of intellectual property; risks related to product liability, recalls and development; risks related to the Company’s management team being subject to a conflict of interest; risks related to the Company’s reliance on its management team for its future performance; risks related to the substantial number of authorized but unissued Shares; risks related to the dilution of the Shares (as defined herein); risks related to the liquidity of the Shares; risks

related to the volatility of the price of the Shares or the market which the Shares trade in; and risks related to income taxes. Forward-Looking Information generally can be identified by the use of forward-looking terminology such as “outlook”, “objective”, “may”, “will”, “expect”, “intend”, “estimate”, “anticipate”, “believe”, “should”, “plans” or “continue”, or similar expressions suggesting future outcomes or events. Such Forward-Looking Information reflects management’s current beliefs and are based on information currently available to management. Some of the factors that may cause actual results to differ materially from those indicated are found in the section “*Risk Factors*” in this AIF.

Forward-Looking Information involves risks and uncertainties that could cause actual results to differ materially from those contemplated by such statements. Factors that could cause such differences include the highly competitive nature of the Company’s industry, government regulation and funding and other such risk factors described herein and in other disclosure documents filed by the Company with Canadian securities regulatory agencies and commissions. This list is not exhaustive of the factors that may impact the Company’s Forward-Looking Information. These and other factors should be considered carefully and readers should not place undue reliance on the Company’s Forward-Looking Information. As a result of the foregoing and other factors, no assurance can be given as to any such future results, levels of activity or achievements and neither the Company nor any other person assumes responsibility for the accuracy and completeness of this Forward-Looking Information. The factors underlying current expectations are dynamic and subject to change.

Although the Forward-Looking Information contained in this AIF are based upon what management believes are reasonable assumptions, there can be no assurance that actual results will be consistent with this Forward-Looking Information. All Forward-Looking Information in this AIF is qualified by these cautionary statements. Other than specifically required by applicable laws, we are under no obligation and we expressly disclaim any such obligation to update or alter the Forward-Looking Information whether as a result of new information, future events or otherwise except as may be required by law. This Forward-Looking Information is made as of the date of this AIF.

## **PART 2            GLOSSARY OF TERMS**

In addition to terms defined elsewhere in this AIF, the following terms, when used in this AIF, will have the following meanings (unless otherwise indicated):

<b>“\$”</b>	means Canadian dollars, unless otherwise specified;
<b>“Acceleration Notice”</b>	has the meaning as set forth in the section entitled “ <i>Three Year History – Year Ended April 30, 2021</i> ”;
<b>“Acceleration Right”</b>	has the meaning as set forth in the section entitled “ <i>Three Year History – Year Ended April 30, 2021</i> ”;
<b>“Advisory Board”</b>	means the advisory board of the Company, as constituted from time to time;
<b>“AIF”</b>	means this Annual Information Form;
<b>“Audit Committee”</b>	means the Audit Committee of the Board;
<b>“Board”</b>	means the board of directors of the Company;
<b>“Broker’s Warrants”</b>	means the non-transferable warrants issued to finders or agents in connection with the IPO or private placements completed by the Company;
<b>“CBCA”</b>	means the <i>Business Corporations Act</i> (Canada);
<b>“CEO”</b>	means chief executive officer;

<b>“CFO”</b>	means chief financial officer;
<b>“Change in Control”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“Common Shares” or “Shares”</b>	means the common shares in the capital of the Company without par value;
<b>“CPABC”</b>	has the meaning as set forth in the section entitled <i>“Directors and Executive Officers – Name, Occupation and Security Holding”</i> ;
<b>“CSE”</b>	means the Canadian Securities Exchange;
<b>“FDA”</b>	U.S. Food and Drug Administration
<b>“FDCA”</b>	has the meaning as set forth in the section entitled <i>“Government Regulations”</i> ;
<b>“First Acceleration Right”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“IDC”</b>	has the meaning as set forth in the section entitled <i>“Intercorporate Relationships”</i> ;
<b>“IIC”</b>	has the meaning as set forth in the section entitled <i>“Intercorporate Relationships”</i> ;
<b>“Incentive Warrant”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2020”</i> ;
<b>“Infringement Notice”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“Inventions”</b>	has the meaning as set forth in the section entitled <i>“Describe the Business – General”</i> ;
<b>“IPO”</b>	means initial public offering;
<b>“Licensed Patent Rights”</b>	means the Patent Rights for UC Cases numbered including extensions of 2005-543, 2015-976, 2017-04-0665, 2015-204, 2005-204, 2015-976, 2019-794, and 2006-740, and for the Licensor’s undivided interest (but not to Varian’s undivided interest) in Patent Rights for UC Case Numbers 2006-740-1 and 2006-740-2.
<b>“License Agreement”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“Licensee”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“License Agreement Milestone”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“Licensor”</b>	has the meaning as set forth in the section entitled <i>“The License Agreement”</i> ;
<b>“LTIP”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“MQSA”</b>	has the meaning as set forth in the section entitled <i>“Describe the Business – General – Breast Cancer Facts and Statistics”</i> ;
<b>“NI 52-110”</b>	means <i>National Instrument 52-110 – Audit Committees</i> ;
<b>“NI 52-110F1”</b>	means 52-110F1 – Audit Committee Information Required in an AIF;

- “NIH”** has the meaning as set forth in the section entitled *“Describe the Business – General”*;
- “Note”** has the meaning as set forth in the section entitled *“Year Ended April 30, 2022”*;
- “Option”** means a stock option to purchase Common Shares;
- “Past Patent Costs”** has the meaning as set forth in the section entitled *“The License Agreement”*;
- “Patent Rights”** means the Licensor’s rights in the claims of the following patents and patent applications:
- (a) U.S. Provisional Patent Application No. 60/677,704, filed May 3, 2005, entitled *“Biopsy Systems for Breast Computed Tomography”*, developed by Drs. John M. Boone and Thomas R. Nelson, and assigned to the Licensor (UC Case No. 2005-543-1; UCSD Case No. 2005-204-1), now abandoned;
  - (b) International Patent Application No. PCT/US06/17146, filed May 3, 2006, entitled *“Biopsy Systems for Breast Computed Tomography”*, developed by Drs. John M. Boone and Thomas R. Nelson, and assigned to the Licensor, (UC Case No. 2005-543-1; UCSD Case No. 2005-204-2), now abandoned, application proceeded into national phase;
  - (c) U.S. Patent Application No. 11/913,494, filed May 3, 2006, entitled *“Biopsy Systems for Breast Computed Tomography”*, developed by Drs. John M. Boone and Thomas R. Nelson, and assigned to the Licensor (UC Case No. 2005-543-2; UCSD Case No. 2005-204-2);
  - (d) U.S. Patent No. 7,394,889, issued July 1, 2008, from U.S. Patent Application No. 11/437,076, filed May 18, 2006, entitled *“Contrast-Enhanced Cone Beam X-Ray Imaging, Evaluation, Monitoring and Treatment Delivery”*, developed by Drs. John M. Boone, et al., and assigned to the Licensor and Varian (UC Case No. 2006-740-1);
  - (e) U.S. Patent No. 7,660,384, issued February 9, 2010, from U.S. Patent Application No. 12/126,224, filed May 23, 2008, entitled *“Contrast-Enhanced Cone Beam X-Ray Imaging, Evaluation, Monitoring and Treatment Delivery”*, developed by Drs. John M. Boone, et al., and assigned to the Licensor and Varian (UC Case No. 2006-740-2);
  - (f) U.S. Provisional Patent Application No. 62/260,169, filed November 25, 2015, entitled *“3D Beam Modulation Filter for Equalizing Dose and Image Quality in Breast CT”*, developed by Drs. John M. Boone, et al., and assigned to the Licensor (UC Case No. 2015-976-1), now abandoned;
  - (g) International Patent Application No. PCT/US16/063701, filed November 23, 2016, entitled *“3D Beam Modulation Filter for Equalizing Dose and Image Quality in Breast CT”*, developed by Drs. John M. Boone, et al., and assigned to the Licensor (UC Case No. 2015-976-2);
  - (h) continuing applications thereof, including divisions, substitutions, extensions and continuation-in-part applications (only to the extent, however, that claims in the continuation-in-part applications are entitled to the priority filing date of the applicable above-listed parent patent application); patents issuing on said applications or continuing applications; reissues of such patents; and corresponding foreign patents or applications of any of the foregoing;

- (i) U.S. Provisional Patent Application No. 62/961,886, filed January 16, 2020, entitled “Multimodal System for Breast Imaging”, developed by Drs. Boone, et al., and assigned to The Regents (UC Case No. 2019-794-1) and continuing applications thereof, including divisions, substitutions, extensions and continuation-in-part applications (only to the extent, however, that claims in the continuation-in-part applications are entitled to the priority filing date of the applicable above-listed parent patent application); patents issuing on said applications or continuing applications; reissues of such patents; and corresponding foreign patents or applications of any of the foregoing; and
- (j) U.S. Patent number 10,548,549, issued February 4, 2020, from U.S. Patent Application No. 15/669,829 filed August 4, 2017, entitled “Measuring Breast Density Using Breast Computed Tomography” developed by developed by Drs. Boone, et al., assigned to the Licensor (UC Case No. 2005-543-003).

<b>“PET”</b>	has the meaning as set forth in the section entitled <i>“Describe the Business – General”</i> ;
<b>“PMA”</b>	has the meaning as set forth in the section entitled <i>“Government Regulations”</i> ;
<b>“PSU”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“QSR”</b>	has the meaning as set forth in the section entitled <i>“Government Regulations”</i> ;
<b>“R&amp;D”</b>	means research and development;
<b>“RAMP”</b>	has the meaning as set forth in the section entitled <i>“Directors and Executive Officers – Name, Occupation and Security Holding”</i> ;
<b>“RSU”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“Scientific Advisory Board”</b>	means the scientific advisory board of the Company, as constituted from time to time;
<b>“Second Acceleration Notice”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“Second Acceleration Right”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2021”</i> ;
<b>“UC Davis”</b>	has the meaning as set forth in the section entitled <i>“Describe the Business – General”</i> ;
<b>“Unit”</b>	means a unit of the Company comprised of one Share and either one Warrant or one-half of one Warrant, as applicable;
<b>“USPTO”</b>	has the meaning as set forth in the section entitled <i>“Three Year History – Year Ended April 30, 2022”</i> ; and
<b>“Warrant”</b>	means a common share purchase warrant of the Company.

## PART 3 CORPORATE STRUCTURE

### 3.1 Name, Address and Incorporation

The Company was incorporated under the CBCA on May 19, 2016 with the name “Izotropic Corporation” and is extra provincially registered in British Columbia.

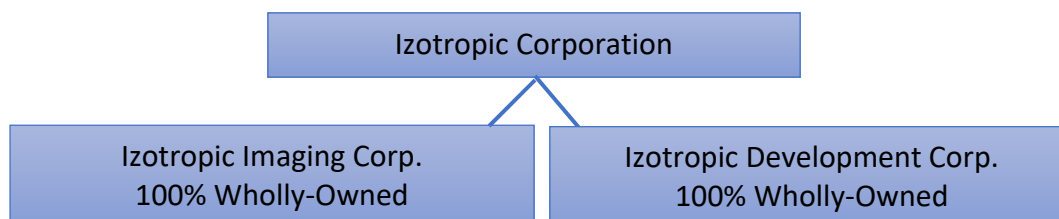
The Company’s head office and registered office is located at Suite 424, 800-15355 24<sup>th</sup> Avenue, Surrey, B.C. V4A 2H9.

The Company is a reporting issuer in the provinces of British Columbia, Alberta, and Ontario. The Shares are listed under the symbol “IZO” on the CSE, “IZOZF” on the OTCQB Venture Market, and “1R3” on the Frankfurt Stock Exchange.

### 3.2 Intercorporate Relationships

The Company has two wholly-owned subsidiaries: Izotropic Imaging Corp. (“**IIC**”), a company incorporated under the laws of the State of Nevada and having its head office and registered office at 15718 39A Avenue, Surrey, B.C. V3Z 0L1 and Izotropic Development Corp. (“**IDC**”), a company incorporated under the laws of the State of California and having its business address at 800 – 15355 24 Avenue, Surrey, B.C. V4A2H9.

The diagram below describes the inter-corporate relationship between the Company, IIC and IDC:



## PART 4 GENERAL DEVELOPMENT OF THE BUSINESS

### 4.1 Three Year History

#### *Year Ended April 30, 2020*

On November 18, 2019, the Company appointed Mr. Ralph Proceviat to the Board and accepted the resignation of Mr. D. Barry Lee.

On February 13, 2020, the Company appointed John McGraw MSc Ph.D. to the Advisory Board.

On February 11, 2020, 6,150,000 Shares were issued for Warrants that were exercised at a price of \$0.20 per Share for proceeds of \$1,230,000 due to a warrant exercise incentive program, whereby for each warrant exercised before February 7, 2020, the holder received one additional warrant (each, an “**Incentive Warrant**”). Each Incentive Warrant entitled the Warrant holder to purchase one additional Share at a price of \$0.20 per Share for a period of two years from the date of issuance.

On April 15, 2020, the Company was issued US Patent No. 10,548,549, entitled “Measuring Breast Density Using Breast Computed Tomography” for a 20-year term, expiring in 2037. This patent covers the use of the Company’s Breast CT Imaging System to measure breast density.

On April 22, 2020, the Company appointed George Burkett, M.Eng. to the Advisory Board.



## **Year Ended April 30, 2021**

On May 7, 2020, the Company was issued US Patent No. 11/913494, entitled “Biopsy Systems For Breast Computed Tomography.” This patent covers the use of Izotropic’s dedicated Breast CT Imaging System for robotic guided biopsy (Izotropic Breast CT Biopsy System), giving physicians the ability to image and obtain samples of suspicious lesions and tumors for pathology testing.

On May 13, 2020, the Company announced it engaged StarFish Medical, Canada’s largest medical device design, development and contract manufacturing company, to complete the final design and development of the Company’s commercial breast CT model, IzoView.

On May 20, 2020, the Company appointed Anita Nosratieh, Ph.D. to the Advisory Board and on May 25, 2020, the Company announced it had engaged the Company advisor and FDA Consultant Anita Nosratieh, Ph.D., to develop and manage the Company’s application for FDA medical device approval of its dedicated Breast CT Imaging System.

On July 6, 2020, the Company announced the appointment of John McGraw, Ph.D., as Executive Vice President of Commercial Operations.

On July 10, 2020, the Board adopted a long-term incentive plan (the “**LTIP**”), for the purpose of attracting, retaining and motivating key individuals. A total of 2,996,549 Common Shares, being 10% of the total number of issued and outstanding Common Shares on the date of adoption of the LTIP, are issuable under the LTIP.

On August 18, 2020, the Company announced it had filed a Pre-Submission Application with the FDA marking the beginning of the market approval process for the Company’s commercial Breast CT Imaging System. This filing is a major milestone for inventors, stakeholders and advocates for breast CT and women’s health. The Company continues an ongoing dialogue with the FDA and is integrating feedback into aspects of the Commercial Breast CT Imaging System.

On August 27, 2020, the Company appointed Ms. Jaclyn Thast as Corporate Secretary of the Company.

On September 15, 2020, the Company appointed Mr. Alexander Tokman as a strategic advisor to the Company’s Advisory Board. The Company granted Mr. Tokman 100,000 Options at an exercise price of \$0.72 expiring in two years.

On October 20, 2020, the Company closed the first tranche of a non-brokered private placement of 4,517,066 Units at a price of \$0.55 per Unit for aggregate proceeds of \$2,484,386. On October 30, 2020, the Company closed the second and final tranche of a non-brokered private placement of 2,866,334 Units at a price of \$0.55 per Unit for aggregate proceeds of \$1,576,484. Each Unit consists of one Share and one Warrant with each Warrant entitling the holder to purchase one Share at a price of \$0.75 per Share for a period of two years following the closing of the offering, subject to an acceleration right such that:

- (i) at any time after the date that is four months and one day after the issue date of the Warrants, if, for at least ten (10) consecutive trading days, the closing price at which the Shares trade on the CSE each day exceeds \$1.25 per Share, the Company may issue a notice (the “**Acceleration Notice**”) to the holder (which Acceleration Notice will be given to the holder by the Company by disseminating a press release) to accelerate the expiry date of the Warrants (the “**First Acceleration Right**”);
- (ii) 50% of the then unexercised Warrants will terminate on the date that is thirty (30) days from the date of the Acceleration Notice in the event that the holder has not exercised the Warrants in accordance with the terms of the Acceleration Notice by such date;
- (iii) at any time after the date that is four months and one day after the issue date, if, for at least ten (10) consecutive trading days, the closing price at which the Shares trade on the Exchange each day exceeds \$1.75 per Share, the Company may issue a notice (the “**Second**

**Acceleration Notice**") to the holder (which Second Acceleration Notice will be given to the holder by the Company by disseminating a press release) to accelerate the expiry date of the Warrants (the "**Second Acceleration Right**" and together with the First Acceleration Right, the "**Acceleration Right**"); and

- (iv) 50% of the then outstanding Warrants will terminate on the date that is thirty (30) days from the date of the Second Acceleration Notice in the event that the holder has not exercised the Warrants in accordance with the terms of the Second Acceleration Notice by such date. For both tranches, an aggregate of \$112,242 finder's fees were paid and an aggregate of 193,995 Broker's Warrants were issued with a fair value of \$118,751. The Broker's Warrants have the same terms and conditions of the Warrants.

On December 9, 2020, the Company closed a non-brokered private placement of 1,896,679 Units at a price of \$0.90 per Unit for aggregate proceeds of \$1,707,011. Each Unit consisted of one Share and one Warrant, with each Warrant entitling the holder to purchase one Share at a price of \$1.50 per Share for a period of two years following the closing of the offering, subject to an acceleration right such that in the event that the Common Shares of the Company have a closing price on the CSE (or such other exchange on which the Common Shares may be traded at such time) of \$1.85 or greater per common share for a period of ten (10) consecutive trading days at any time from the date that is four months and one day after the closing date of the offering, the Company may accelerate the expiry date of the Warrants by giving notice to the holders thereof (by disseminating a news release advising of the acceleration of the expiry date of the Warrants) and, in such case, 100% of the then unexercised Warrants will expire on the thirtieth (30<sup>th</sup>) day after the date of such notice. Finders' fees of \$64,087 were paid and 62,947 Broker's Warrants were issued with a fair value of \$37,159. The Broker's Warrants have the same terms and conditions of the Warrants. All securities issued in connection with the offering were subject to a statutory hold period expiring four months and one day after closing of the offering.

On December 15, 2020, the Company announced it had completed the pre-submission meeting with the FDA and came away with a high degree of confidence going forward. The meeting focused on 4 key areas: product and indication for use statements, device labeling terms, and clinical and validation study designs to verify future breast CT marketing claims. The Company's scientific and commercialization teams met after receiving the finalized minutes and feedback from the FDA and have set action items to accelerate objectives focused on engineering, clinical trial planning, and payor engagements to bring breast CT to the market.

On January 7, 2021, the Company announced the addition of Jeff Siewerdsen Ph.D. to the Company's Scientific Advisory Board, comprised of industry experts and authorities in their respective fields. Dr. Siewerdsen was granted 100,000 Options at a price of \$1.25 with a two-year term.

On January 11, 2021, pursuant to the LTIP the Company issued 1,550,000 Restricted Stock Units (each, an "**RSU**") to advisors, consultants and a director. The RSU's vest either four tranches over 1.5 years or based on achieving performance milestones. At April 30, 2021, 662,500 of the RSU's had vested. The Company recognizes the share-based payment expense over the vesting terms and for the year ended April 30, 2021 recognized \$1,192,849, and of the total issued, 662,500 were vested. The share-based compensation costs for RSUs granted are based on the share price at the date of grant at a price of \$1.23 per RSU.

On January 11, 2021, pursuant to the LTIP the Company issued 500,000 Performance Stock Units (each, a "**PSU**") to the Company's Commercial Operations Executive, with a vesting schedule determined by performance (milestone) based incentives. For the year ended April 30, 2021, the Company recognized share-based payment expense of \$38,256 relating to the PSU's.

On February 3, 2021, the Company upgraded its U.S. listing to the OTCQB Venture Market under the symbol "IZOZF".

On February 9, 2021, the Company unveiled its highly anticipated breast CT platform, IzoView. The Company has filed a number of trademark applications to protect the Company's recognizable name, platform device name, and logos.

On March 15, 2021, the Company announced the appointment of Dr. John McGraw as CEO, effective April 5, 2021. Dr. McGraw replaces Mr. Robert Thast, who has resigned from his position as President and CEO and will remain a director and special advisor.

On March 24, 2021, the Company announced a partnership with EXCITE International, a global network of payors, health systems, patients, scientists, and end-users, to prepare for future commercial adoption of IzoView.

On April 20, 2021, the Company announced the appointment of Dr. Tao Wu to its Scientific Advisory Board.

### ***Year Ended April 30, 2022***

On June 6, 2021, the Company announced it has adjusted its business plan to its benefit after factoring the challenges of running a clinical study during the COVID-19 pandemic and the availability of next-generation primary device components, including upgraded hardware, software. The Company also announced projected timelines to the clinical study and fabrication of initial IzoView units.

On June 30, 2021, the Company appointed Dr. Younes Achkire as Executive Vice-President of Product Engineering. The Company granted certain advisors and consultants 450,000 Options at an exercise price of \$0.74 expiring in two years.

On September 8, 2021, the Company announced it received a Notice of Allowance in response to a patent application from the U.S. Patent and Trademark Office (“**USPTO**”). The patent pertains to a specialized 3D x-ray filter, known as a 3D-Beam Modulation Filter, that is designed to tailor the shape of the IzoView x-ray beam to match the shape of the patient’s breast being scanned. The 3D filter provides benefits for both the patient and the imaging output by maximizing image quality while minimizing the radiation dose to the breast.

On September 9, 2021, the Company announced it received a semi-finalist nomination for AuntMinnie.com’s 2021 award campaign to recognize the best and brightest in medical imaging. Auntminnie.com, a leading radiology news website, has recognized IzoView in the Best New Radiology Device category.

On September 21, 2021, the Company announced it entered into an agreement with Johns Hopkins University School of Medicine to develop image reconstruction software (deep machine learning algorithms) to further improve the image processing performance of Breast CT while minimizing computational burden. The software will integrate into the fabrication of the Company’s initial IzoView clinical study units.

On October 13, 2021, the Company announced that it completed its third quarter milestones as previously announced and that fabrication of IzoView was underway ahead of schedule. The Company plans to meet its first quarter 2022 milestones as scheduled.

On October 25, 2021, the Company announced its October 2, 2021 Annual General Meeting results, in which Mr. Marshal Severyn resigned from the Board, Company CEO, Dr. John McGraw, was elected to the Board, and Dale Matheson Carr-Hilton LaBonte LLP was appointed auditor for the following year.

On November 5, 2021, the Company appointed Dr. Andrew M. Hernandez as Head of Imaging Technology.

On November 22, 2021, the Company announced that its engineering teams successfully built and assembled IzoView’s radiation imaging subsystem, and was now taking static images, to be characterized and optimized for 360-degree image acquisition.

On November 29, 2021, the Company announced that it implemented a Quality Management System for regulatory and manufacturing purposes.

On March 7, 2022, the Company announced that it was bringing its medical device engineering and product development to its in-house facility in Sacramento, California.

On March 14, 2022, Dr. Shadi Aminololama-Shakeri joined the Company's advisory board and commercialization team as a clinical consultant.

On April 4, 2022, the Company completed a non-brokered private placement of unsecured promissory notes (each, a "Note") pursuant to which the Company issued: (i) Notes purchased for an aggregate price of \$2,050,000 with the option for the Company to acquire an additional \$2,000,000 subject to terms that will be determined at a later date, and (ii) 826,613 Warrants, 403 Warrants for every \$1,000 of principal of the Notes. Each Warrant is exercisable into one Share at an exercise price of \$0.62 per Share for a period of two (2) years from the date of closing, being March 31, 2023. The Notes will mature on the date that is one year from the date of issuance. The Notes will either: (i) bear simple interest at 1% per month, from the date of issuance, payable every three months; or (ii) be subject to an original issuance discount in lieu of interest. It was the intention of the Company that the proceeds from the offering would be used for completing the initial IzoView device build, engaging a clinical research organization to undertake the clinical study for FDA market authorization, and working capital. All securities issued in connection with the offering were subject to a statutory hold period of four months and one day from the date of issuance in accordance with applicable securities legislation. The Company did not pay any finder's fees in connection with the offering.

On April 18, 2022, the Company announced partnerships with new consultants for investor awareness and investor relations services, including Blaze Capital and Westmount Capital. The Company agreed to pay: (i) Blaze Capital \$50,000 USD with coverage initiating April 19, 2022 and (ii) Westmount Capital 8,000 CHF per month for an initial 3-month term and 200,000 stock options, priced at \$0.65 with a term of 1 year, vesting 50% after 30 days and 50% after 90 days.

On April 19, 2022, the Company engaged GRIT Capital to bring awareness to the Company's profile within the modern Gen Z and Millennial investor age demographics, for a six-month term that would commence the first week of May, 2022. Under the terms of the agreement, the Company issued 181,495 Common Shares to GRIT Capital at a deemed price of \$0.66 per Share. The Shares issued were subject to a hold period of four months and one day from the date of issuance.

#### ***Subsequent to Year Ended April 30, 2022***

On May 10, 2022, the Company unveiled the commercial prototype device design that will be used in forthcoming clinical studies for market authorization in the U.S. A photorealistic 3D animation detailing IzoView's design, functionality, and capabilities is now live on the Company's YouTube channel. The Company has begun filing patents to protect unique and important features of the IzoView Breast CT System.

On June 29, 2022, the Company announced timeline updates for the initial IzoView commercial prototype build and commented on supply chain issues, engineering updates, and the design of the clinical study.

On July 19, 2022, the Company engaged a clinical research organization, ICON plc, to help prepare for its upcoming clinical study and submission for market authorization in the U.S.

On August 11, 2022, the Company successfully relocated IzoView and associated components and completed the transition of all major medical device engineering and product development operations to California.

On November 1, 2022, the Company granted 2,160,000 Options at an exercise price of \$0.61 expiring in five years to certain advisors, consultants, and a director of the Company.

## **4.2 Significant Acquisitions**

During the year ended April 30, 2022, the Company did not complete any significant acquisition for which disclosure is required under Part 8 of National Instrument 51-102 *Continuous Disclosure Obligations*.

## **PART 5            DESCRIBE THE BUSINESS**

### **5.1      General**

Izotropic is the only publicly-traded company engaged in the development and commercialization of a dedicated breast CT imaging platform, IzoView, for the more accurate detection of breast cancers, to address the growing demand by the breast imaging medical community for cost-effective, true 3D, high resolution breast imaging. The Company does not currently generate revenue.



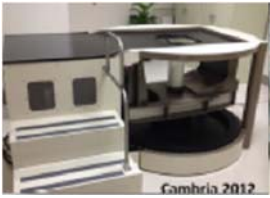
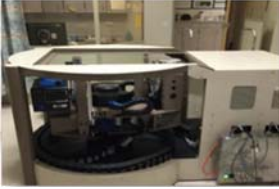
IzoView will produce high resolution breast images in true 3D and is ideal for imaging patients including those with dense breast tissue. A single 10 second scan acquires approximately 500 images, without breast compression or continual technician breast handling to position the breast, providing a more comfortable patient experience. Enhanced image reconstruction software is currently in development in partnership with Johns Hopkins University School of Medicine that will utilize the latest machine learning algorithms to deliver both high resolution and low noise images at low radiation dose levels.

The Company's initial clinical study for submission to the FDA will demonstrate superior performance of diagnostic breast CT imaging over diagnostic mammography procedures. IzoView is being developed as a platform system. Platform applications will be developed and brought to market in accordance with each market's respective regulatory agency's guidelines. After initial market authorization, the Company will investigate platform applications including breast screening in radiology, treatment planning and monitoring in surgical oncology, and breast reconstruction and implant monitoring in plastic and reconstructive surgery.

The Company's business strategy is to complete the development of breast imaging technology for diagnosis of breast cancer and commercialize IzoView through various revenue methods including capital equipment sales, lease payments, or pay-per-use, providing customers (hospitals and clinics) with options which meet their unique needs. Additional revenue items will include maintenance contracts, sterile disposables, software feature upgrades, and additional hardware modules. The Company's entire rights to the technology are based upon the License granted by the Licensor pursuant to the License Agreement. The Company holds the exclusive License to the inventions entitled "Breast CT for Early Cancer Detection and Diagnosis", "Contrast-Enhanced Cone Beam X-Ray Imaging, Evaluation, Monitoring and Treatment Delivery", "Biopsy Systems for Breast Computed Tomography", "Measuring Breast Density Using Breast Computed Tomography", "Multimodal System for Breast Imaging", and "3D Beam Modulation Filter for Equalizing Dose and Image Quality in Breast CT" (the "**Inventions**") as described in the Licensed Patent Rights. The initial product of the Company that it intends to commercialize is expected to be known as the "IzoView" and will include the fifth-generation (commercial model) breast CT imaging unit, previously defined as the Commercial Unit. As described below under "*The Commercial Unit*", the Company intends to enter into an agreement with a major medical equipment leasing company that would provide 100% of the capital required to build the Commercial Units to finance the construction of Commercial Units for market in future. After final development and regulatory approval, the Company intends to launch and distribute IzoView primarily to hospitals and clinics throughout the U.S. and follow with additional jurisdictions and the commercialization other related breast CT technologies (platform applications) and products in the future.

#### ***History of the Izotropic Breast CT Imaging System***

Since 2001, over US\$19 million in research funding from the National Institutes of Health (previously defined as the "**NIH**") and other grant sources has been invested developing, building, and testing four successive generations of IzoView, previously known as the Isotropic Breast Imaging System, by researchers at the University of California, Davis ("**UC Davis**"). The four prototypes developed to date are described in the table below:

Prototype	Photo	Status	Description
<b>Albion</b>	 A photograph of the Albion 2004 breast CT scanner, which is a compact, light blue machine with a circular gantry and a patient bed.	Completed in 2004.	Albion was used to acquire a large number of initial cases, both with and without contrast injection.
<b>Bodega</b>	 A photograph of the Bodega 2007 breast CT scanner, a larger, tan-colored machine with a more complex gantry and a patient bed.	Completed in 2007.	Bodega was similar to Albion except that it had a slightly more powerful X-ray tube and the gantry was larger, allowing placement of a positron-emission tomography (“PET”) system. This scanner produced the first dedicated breast PET/CT scans in humans.
<b>Cambria</b>	 A photograph of the Cambria 2012 breast CT scanner, an open-design machine with a large gantry and a patient bed.	Completed in 2012.	Cambria had an open design, requiring no shielding around the scanner. This scanner provided additional cases to the breast CT image database compiled by researchers at UC Davis.
<b>Doheny</b>	 A photograph of the Doheny breast CT scanner, a modern, white machine with a large gantry and a patient bed.	Completed in 2014.	Doheny is the current breast CT scanner in the laboratory at UC Davis. It has higher spatial resolution than all previous models and serves as the basis for the Commercial Unit. This scanner is currently being used for final clinical testing in humans under NIH funding, and the imaging hardware for this is the basis for the Isotropic Breast Imaging System. Doheny also has PET capabilities for research, however, PET will not be a part of the Commercial Unit, at least initially as PET technology adds significant cost without providing measurable advantage to the system’s cancer detection capabilities. This breast CT imaging system utilizes a full 360-degree rotation around the breast to acquire approximately 500 images in approximately 10 seconds. Using custom reconstruction software, the system creates a full 3D reconstruction of the breast, with volume elements (voxels) on the order of 0.25 mm x 0.23 mm x 0.23 mm. Each breast CT image is over a million pixels in size, and each breast, depending on length, uses about 500 images, for a total of a half billion voxels per breast. Engineers, physicists, radiologists and other researchers at UC Davis continue to work on design aspects of the Doheny system, including the breast positioning design, tabletop, positioning aids, specialized X-ray beam shaping filters, and many other subtleties to improve the scanner’s clinical performance.

### ***Clinical Studies***

Researchers at UC Davis have invested significant time to develop the technology behind IzoView and have undertaken a number of clinical studies. UC Davis, in cooperation with the University of Pittsburgh Medical Center, conducted studies on 600 high risk breast cancer patients using the second-generation CT imaging/scanning unit, named Bodega, which was completed in 2007. Researchers at UC Davis reviewed the results of those studies and further enhancements resulted in the third and fourth generation CT imaging/scanning units, Cambria and Doheny, respectively developed by engineers and physicists at UC Davis. A second clinical study of 400 high risk female breast cancer patients is currently underway at UC Davis Medical Center and is fully funded through grants made by the NIH and expects to compare both screening and diagnostic aspects of breast CT imaging systems. The studies for breast CT are currently ongoing at UC Davis Medical Center in Sacramento, CA.

Research to date includes thousands of images taken on hundreds of patients using the earlier versions of the Izotropic Breast Imaging System. Based on the results of these images, among other factors, the Company's management believes that the Company's technology is superior to the current standard-of-care diagnostic mammography for more accurate detection and diagnosis of breast cancer in women.

These studies of earlier breast CT model's technical performance and computer simulation of breast lesion (abnormalities) detection using the extensive breast image database—with human observer validation of simulation results—have demonstrated that breast CT may outperform mammography-like breast imaging for detecting tumor masses and other lesions. In studies where contrast was used during the procedure (similar to contrast enhancement in magnetic resonance imaging of the breast), high detection performance was achieved in all types of breast lesions. It is likely that contrast-enhanced breast CT has very similar cancer detection performance to the other true 3D imaging platform of contrast-enhanced breast MRI, but at a fraction of the cost. Furthermore, IzoView requires approximately 20% of the floor space needed for an MRI system, making it an appealing option for space-constrained facilities.

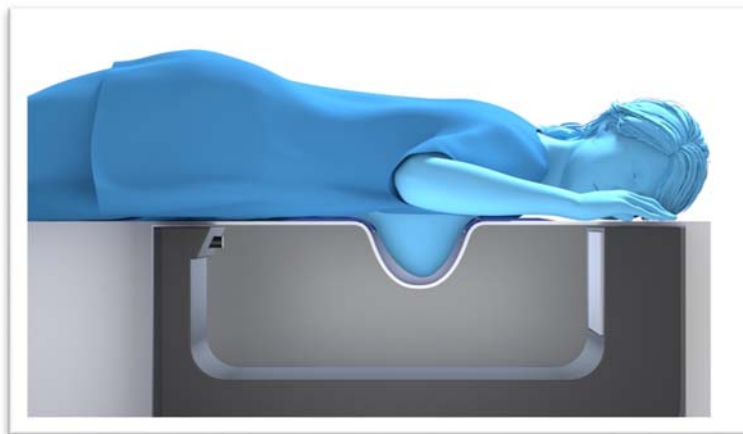
### ***IzoView Technology***



Both traditional digital mammography and digital tomosynthesis, which are sometimes marketed as 3D mammography, are 2D and 2.5D imaging technologies, respectively, that both require the breast be compressed between two imaging plates. Compression requires a technician handle a patient's breast and can be uncomfortable or painful. Compression also distorts anatomical structures, differentiation between cancer indicating macro and micro-calcifications is very limited, and is not well-suited for imaging patients with dense breasts.



*Conceptual image of IzoView Breast CT*



*Illustrative side view of IzoView Imaging Cup and Imaging Hardware beneath patient*

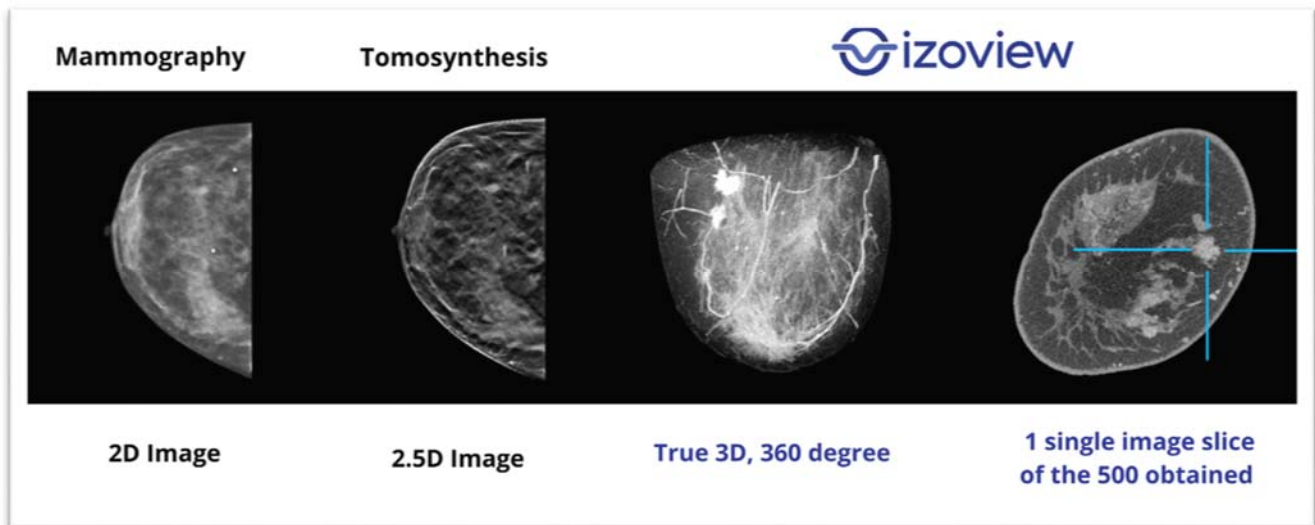
With IzoView, the patient lays face down on the system table placing the breast to be imaged in a cup in the table. The imaging hardware beneath the table circles 360-degrees around the breast creating a series of approximately 500 cross-sectional raw-data images. These raw images are then processed by proprietary computer software and reconstructed into three-dimensional image of the breast. These images can be viewed from any angle like a 3D model, or by individual cross-sections, or by the three normal viewing planes radiologists are accustomed to; coronal, sagittal and axial.

IzoView does not utilize breast compression. The patient is empowered by placing their own breast in the imaging cup in the system table, and the internal breast structures are preserved in their natural orientation. IzoView has a radiation dose is comparable to 2-view mammography, and is ideal for imaging patients with dense breast tissue.

The IzoView system is intended to be used with routinely used generic CT contrast agents that are intravenously administered and are currently on the market today. CT contrast agents are significantly better at identifying malignant tumors compared to non-contrast enhanced images.

The IzoView system is also different than widely available whole-body CT systems that circle a patient's body to collect images of interest. The use of contrast is well established in whole-body CT imaging. The IzoView scan is precisely dedicated to the target breast.





*Images of breast CT taken with previous generation device at UC Davis*

***The Commercial Unit***

Working with a collaborative of in-house engineers and scientists along with the inventors and clinicians, the Company plans to complete the design and development of the first IzoView unit for use in its clinical study by the end of Q4 of 2022. This collaboration has supported design and development and will enable further technical improvement and facilitate additional products and clinical studies. The Commercial Unit also draws on nearly 20 years of research and development by inventors Dr. John Boone, professor and medical physicist at UC Davis, and Dr. Thomas R. Nelson, along with many graduate students and senior academic collaborators at UC Davis in Sacramento, CA. Four successive breast CT imaging systems have been built at UC Davis Medical Centre. Each of these systems had better clinical utility and image performance than its predecessor. The latest system has incorporated lessons learned from previous models, and the incorporation of state-of-the-art subcomponents have improved clinical utility with exceptional high-resolution CT images of the breast.

The initial IzoView prototype (first build before the first clinical study unit) was intended to be completed at the end of Q1 of 2022. In Q1 of 2022, the Company released new renderings of the IzoView prototype and, due to supply chain issues, the Company revised the timeline. The Company anticipates that the initial IzoView prototype will now be completed by Q4 of 2022. Design considerations including but not limited to manufacturability, transportability, human factors and user experience, and access to components for maintenance were factored into IzoView when additional modifications to the design were made in the Spring of 2022 which included improvements such as manufacturability and increased flexibility on utilization of various parts.

The costs associated with the initial run of IzoView units is not being disclosed at this time, however, the Company is working on a plan to provide high resolution 3D Breast CT in competition with 2.5D technology Tomosynthesis, and far below the only other true 3D technologies which are whole-body CT and MRI.

***Business Model***

The Company has an executive and management team with experience in the diagnostic and therapeutic medical imaging market, specifically experienced from design, engineering, manufacturing, and sales.

Revenues will be derived through a combination of leasing, sales and per customer usage models, all of which would have recurring and or additional revenue components, regardless of the transaction method. The Company intends to focus on revenue-sharing agreements with customers (where possible), through capital leasing and outright sales. The Company has expressions of interest with capital finance organizations and a relationship has been developed with a

major medical equipment leasing company that could provide the total capital required to build Units for the market, subject to approved credit applications from customers.

**Technical Performance Comparison Table**

Compared to present breast imaging technologies in the marketplace, the breast CT technology is the only one that has all the following key attributes as shown in the table below:

	Breast CT	2D Mammography	2.5D Tomosynthesis	Magnetic Resonance Imaging	Ultrasound
True 3D	✓			✓	✓
No compression	✓			✓	✓
No risk of breast implant rupture due to lack of mechanical compression	✓			✓	✓
Not claustrophobic	✓	✓	✓		✓
Low radiation dose	✓	✓	✓	✓	✓
Optimal use of contrast	✓			✓	
Short scan time (high patient throughput)	✓	✓			
3D spatial resolution of internal breast structures	✓			✓	
Specificity	✓	✓	✓	✓	?
Ability to discriminate between benign and malignant masses	✓			✓	
Ability for density measurements	✓			✓	

**The License Agreement**

On April 25, 2017, the Company (the “Licensee”) entered into a license agreement (the “License Agreement”) with the Regents for the University of California (the “Licensor”), which granted the Licensee an exclusive license to the Licensed Patent Rights. In consideration for the License, the Licensee agreed to pay the Licensor:

- a cash payment of US\$10,000 due within 30 days from entry into the License Agreement (subsequently paid);
- a cash payment of US\$200,000 due within 30 days of the following:

- a change of control transaction (a “**Change of Control**”), which means the acquisition, merger, reorganization or other transactions where more than 50% of the voting power of the Company or IIC is transferred to a third party, and,
- a financing of the Company whereby either the Company or IIC issues of debt or equity securities of the Company or IIC, as the case may be, in one or more bona fide financing transactions with cumulative gross proceeds of at least US\$3,000,000, excluding the conversion of any convertible debt and in which the cumulative gross proceeds to be received by either the Company or IIC, as the case may be, are principally from venture capital, private equity, or similar types of investors. Having raised over \$5,000,000.00 in the fourth quarter of 2020 the Company made this payment and met this obligation.
- a cash payment of 2% of total consideration received by the Company within 30 days of the completion of a Change of Control;
- 3% of net sales from the sales of all products produced by the Licensee in connection with the License Agreement and sold by the Company in the U.S.;
- 3% of net sales from the sale of the first 15 commercial sales of all products produced by the Licensee in connection with the License Agreement in any other country excluding the U.S.; and
- 1% royalty of net sales of all methods and services sold by the Licensee in connection with the License Agreement.

Under the License Agreement, the Licensee may grant a sublicense to affiliates of the Company, or to third parties. The License Agreement sets out certain conditions that will apply to any grant of a sublicense. The Licensee has agreed to pay the Licensor 25% of any cash consideration, or the cash equivalent of any other form of consideration, due to the Licensee for the grant of rights under a sublicense.

Under the License Agreement, the Licensee is obligated to further development, manufacture, marketing and sale of products, methods, and services offered by the Licensee in connection with the License Agreement in quantities sufficient to meet the market demand. Under the License Agreement, the Licensee is obligated to complete the following milestones (each, a “**License Agreement Milestone**”):

- submit an application covering a product or service to be offered by the Licensee in connection with the License Agreement to the FDA or equivalent foreign agency by June 30, 2018. The timeline to accomplish this condition was later revised and extended and the Company initially engaged with the FDA in the third quarter of 2020.
- obtain FDA or equivalent foreign agency approval by December 31, 2021. This condition has also been revised and timeline extended for up to 7 years. The Company will make annual payments of up to \$15,000 until this milestone is accomplished.
- achieve the first commercial sale and fill the market demand of products or services to be offered by the Licensee under the License Agreement in the U.S. by June 30, 2022. This milestone timeline has also been revised for up to 7 years based on a number of factors (see below), and been articulated in amendments to the License.

If the Licensee is unable to meet any of the above License Agreement Milestones, the Licensee has the right to extend the target date of any License Agreement Milestone for a period of twelve months upon the payment of US\$10,000 to the Licensor. The Licensee has a further right to extend the target date of any License Agreement Milestone for an additional 12 months upon a payment of US\$15,000 to the Licensor. Under the License Agreement, the total period of time to complete any License Agreement Milestone must not exceed seven years from the date of the License Agreement, unless the parties mutually agree in writing otherwise. If the Licensee does not complete a License Agreement Milestone and does not opt to extend the period to complete the License Agreement Milestone, or opts to

extend the period to complete the License Agreement Milestone and does not complete the License Agreement within the extended time period, then the Licensor has the right to terminate the License Agreement, or reduce the Licensee's exclusive License to a non-exclusive license. The Licensor may also terminate the License Agreement under certain other conditions.

Under the License Agreement, the Licensor is responsible for all patent prosecution in connection with the Licensed Patent Rights. However, the Licensee has agreed to pay (or reimburse, as the case may be) the Licensor, for all past, present, and future costs for preparing, filing, prosecuting, and maintaining all patent applications and patent under the Patent Rights. With regard to past patent costs, the Licensee is obligated to pay the Licensor the sum of US\$79,871.80 (the "**Past Patent Costs**") in accordance with the following schedule:

- one-third of the Past Patent Costs due on or before April 25, 2018 (payment completed); and
- one-third of the Past Patent Costs due on or before April 25, 2019 (payment completed); and
- one-third of the Past Patent Costs due on or before April 25, 2020 (payment completed).

If the Licensee learns of the substantial infringement of any Patent Rights, the Licensee will promptly provide the Licensor with notice and reasonable evidence of such infringement (the "**Infringement Notice**"). The Licensor and the Licensee agree to use diligent efforts, in cooperation with each other, to terminate such infringement without litigation. If, after ninety days following the effective date of the Infringement Notice, the infringing activity has not abated, the Licensee may initiate suit for patent infringement against the infringer. If, in a suit initiated by the Licensee, the Licensor is involuntarily caused to be joined as a party, the Licensee agrees to pay any costs incurred by the Licensor arising out of such suit, including any legal fees of legal counsel of the Licensor. If, within 120 days of the effective date of an Infringement Notice, the infringing activity has not abated and if Licensee has not initiated a suit against the infringer, then Licensor may initiate suit for patent infringement against the infringer and the Licensee may not join such suit without the consent of the Licensor.

### ***Licensed Patent Rights***

Under the License Agreement, the Company was granted the License to the Licensed Patent Rights from the Licensor. One of the patent-pending applications, known as UC Case 2005-543 and which relates to the Invention named "Breast CT for Early Cancer Detection and Diagnosis" under the Licensed Patent Rights was split into five groups by the USPTO. Each patent application submitted to the USPTO goes through a prosecution process. To date only one of the five groups of the Licensed Patent Rights has been prosecuted. Currently, two other groups, the Milestone Patents, which are included in the Licensed Patent Rights, are being prosecuted by the Licensor with funding provided by the Company. One group, known as UC Case 2006-740-1 and 2006-740-2, and which relates to the Invention named "Contrast Enhanced Cone Beam X-ray Imaging, Evaluation, Monitoring and Treatment Delivery" under the Licensed Patent Rights describes novel methods for using the breast CT data sets to evaluate and quantify breast density. Breast density has been identified as an important characteristic that can be included in a patient risk profile, which can be used in designing a personalized breast cancer screening program. Another licensed patent-pending application under the Licensed Patent Rights, known as UC Case 2015-976 and which relates to the Invention named "3D Beam Modulation Filter for Equalizing Dose and Image Quality in Breast CT" involves a three-dimensional beam shaping filter to optimize image quality and radiation dose. This system also involves a breast immobilization technology, which does not involve breast compression. The immobilization technology may greatly increase patient comfort while maintaining the breast in the most optimal position for imaging. The table below further describes the Inventions that have been disclosed:

UC Case No.	Title	Patent Status	Issued Patent Number or Application Number
2005-543-2 2005-204-2	Biopsy Systems For Breast Computed Tomography	Issued	10,492,749
2005-543-4	Biopsy Systems For Breast Computed Tomography	Issued	10,842,455
2005-543-3	Measuring Breast Density Using Breast Computed Tomography	Issued	10,548,549
2005-543-5	Biopsy Systems For Breast Computed Tomography	Pending	17/079,262
2005-543-6	Biopsy Systems For Breast Computed Tomography	Pending	17/180,549
2015-976-3	3D Beam Modulation Filter For Equalizing Dose And Image Quality In Breast CT	Notice of Allowance	11,076,821
2015-976-4	3D Beam Modulation Filter For Equalizing Dose And Image Quality In Breast CT	Continuation Application, Pending	17/356,249
2019-794	Contrast-Enhanced Cone Beam X-Ray Imaging, Evaluation, Monitoring And Treatment Delivery	Issued	7,394,889
2019-794	Contrast-Enhanced Cone Beam X-Ray Imaging, Evaluation, Monitoring And Treatment Delivery	Issued	7,660,384

## **Government Regulations**

The Company anticipates that the Commercial Unit will be subject to extensive and rigorous regulation by the FDA and other countries or regions in which the Company markets IzoView.

### *United States*

The FDA regulates the development, testing, manufacturing, labeling, storage, recordkeeping, promotion, marketing, distribution, and service of medical devices in the U.S. to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the U.S. to international markets and the importation of medical devices manufactured abroad.

Unless an exemption applies, each new or significantly modified medical device the Company seeks to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act, (the “**FDCA**”), also referred to as a 510(k) clearance, or approval from the FDA of a pre-market approval (“**PMA**”) application. Both the 510(k) clearance and PMA processes can be expensive, and lengthy, and require payment of significant user fees, unless an exemption is available.

Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. IzoView will be considered a Class III device. Class III devices are subject to the PMA application process, which is generally costlier and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA’s satisfaction. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA’s satisfaction reasonable assurance of the safety and effectiveness of the device for its intended use.

In addition, after a device is placed on the market, numerous FDA and other regulatory requirements continue to apply. These include establishment registration and device listing with the FDA; compliance with medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and compliance with corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health. The FDA and the Federal Trade Commission also regulate the advertising and promotion of the Company’s products to ensure that the claims the Company may make are consistent with the Company’s regulatory clearances, that there is scientific data to substantiate the claims and that the Company’s advertising is neither false nor misleading. In general, the Company may not promote or advertise its products for uses not within the scope of the Company’s intended use statement in the Company’s clearances or make unsupported safety and effectiveness claims. Many regulatory jurisdictions outside of the U.S. have similar regulations to which the Company is subject.

The Company’s manufacturing processes are required to comply with the FDA’s Good Manufacturing Practice requirements contained in its Quality System Regulation (“**QSR**”) and associated regulations and guidance. The QSR covers, among other things, the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all medical devices intended for human use. The QSR also requires maintenance of extensive records which demonstrate compliance with FDA regulation, the manufacturer’s own procedures, specifications and testing as well as distribution and post market experience. Compliance with the QSR is necessary to receive FDA clearance or approval to market new products and is necessary for a manufacturer to

be able to continue to market cleared or approved product offerings in the U.S. A company's facilities, records, and manufacturing processes are subject to periodic scheduled or unscheduled inspections by the FDA, which may issue reports known as Forms FDA 483 or Notices of Inspectional Observations which list instances where the FDA inspector believes the manufacturer has failed to comply with applicable regulations and/or procedures. If the observations are sufficiently serious or the manufacturer fails to respond appropriately, the FDA may issue a "Warning Letter", or "Untitled Letter", which are notices of intended enforcement actions against the manufacturer. If a Warning Letter or Untitled Letter is not addressed to the satisfaction of the FDA, or if the FDA becomes aware of any other serious issue with a manufacturer's products or facilities, it could result in fines, injunctions, civil penalties, delays, suspension or withdrawal of clearances, seizures or recalls of products, operating restrictions, total shutdown of production facilities, prohibition on export or import and criminal prosecution. Such actions may have further indirect consequences for the manufacturer outside of the U.S. and may adversely affect the reputation of the manufacturer and the product. In the U.S., routine FDA inspections usually occur every two years, and may occur more often for cause.

To a greater or lesser extent, most other countries require some form of quality system and regulatory compliance, which may include periodic inspections, inspections by third party auditors, and specialized documentation. Failure to meet all the requirements of these countries could jeopardize the Company's ability to import, market, support and receive reimbursement for the use of IzoView and the Commercial Unit in these countries.

Products manufactured outside the U.S. by or for the Company are subject to U.S. Customs and FDA inspection upon entry into the U.S. The Company must demonstrate compliance of such products to regulations in the U.S. and carefully document the eventual distribution or re-exportation of such products. Failure to comply with all applicable regulations could prevent the Company from having access to products or components critical to the manufacture of finished products and lead to shortages and delays.

#### *FDA Pre-Submission Meeting*

In Q3 of 2020, the Company completed a pre-submission meeting with the FDA. Representation included the scientific and commercialization teams, engineering and regulatory advisors, and the project management team from engineering firm StarFish Medical. The meeting focused on 4 key areas: product and indication for use statements, device labeling terms, and clinical and validation study designs to verify future IzoView marketing claims.

Izotropic will continue its work with the FDA in a series of ongoing discussions including early collaboration meetings leading to an investigational device exemption (IDE) submission for an IDE approval by the FDA. This will enable IzoView to be used as an investigational device in a clinical study to collect safety and effectiveness data.

#### *Clinical Study Design for FDA Market Authorization*

The initial indication for IzoView is intended for diagnostic imaging of the breast for patients with suspicious findings on screening mammography. IzoView is not intended for breast cancer screening for the clinical study designed for the company's initial market authorization in the U.S. The study design is to compare images acquired on IzoView utilizing contrast-enhancement (CE) with an iodine-based contrast agent in comparison to non-contrast-enhanced diagnostic mammography. This is a multi-reader, multi-case superiority study. Specifically, readers will assess both diagnostic mammography and CE-IzoView breast CT images and their assessment will be compared to the final clinical diagnosis. The subject's final clinical diagnosis for the study is determined by 1-year follow-up or subsequent histopathology result from a biopsy. Subjects that have a negative finding at 1 year will be classified as having a final diagnosis of "no cancer". Discovery of a cancer at any time up to and including the first year after initial diagnostic mammography examination resulted in the subject being assigned a final diagnosis of cancer.

Izotropic may have up to four clinical sites in the U.S. with total participant recruitment may take one to two years depending on a variety of factors including, but not limited to, recruitment capability and cancer positivity rate at a site.

## *Foreign Regulation*

In order for the Company to market IzoView and commercial systems in other countries, the Company must obtain market authorization and comply with extensive product and quality system regulations in other countries. These regulations, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Some countries have regulatory review processes which are substantially longer than processes in the U.S. Failure to obtain regulatory approval in a timely manner and to meet all local requirements including language and specific safety standards in any foreign country in which the Company plans to market its products could prevent the Company from marketing products in such countries or subject the Company to sanctions and fines.

Izotropic intends to apply for market authorization for IzoView in the European Union (EU) and Canada following a PMA submission to the FDA.

Regulations in other countries, including the requirements for approvals or clearance and the time required for regulatory review, vary from country to country. Certain countries have their own regulatory agencies. These regulations typically require regulatory approvals and compliance with extensive safety and quality system regulations. Failure to obtain regulatory approval in any foreign country in which the Company plans to market IzoView, or failure to comply with any regulation in any foreign country in which the Company markets IzoView, may negatively impact the Company's ability to generate revenue and harm its business. In addition, local regulations may apply which govern the use of the Company's products and which could have an adverse effect on the Company's product utilization if they are unfavorable. All such regulations are revised from time to time and in general are increasing in complexity, and in the scope and degree of documentation and testing required. There can be no assurance the outcomes from such documentation and testing will be acceptable to any particular regulatory agency or will continue to be acceptable over time. There are further regulations governing the importation, marketing, sale, distribution, use and service as well as the removal and disposal of medical devices. Failure to comply with any of these regulations could result in sanctions, fines and prevent the Company from marketing its products in these regions.

## *Other Healthcare Laws*

The Company may also be subject to federal and state healthcare laws and regulations pertaining to fraud and abuse, physician payment transparency and privacy and security laws and regulations. If the Company's operations are found to violate any of the laws described above or any other laws and regulations that apply to the Company, it may be subject to penalties, including civil and criminal penalties, damages, fines, the curtailment or restructuring of the Company's operations, the exclusion from participation in federal and state healthcare programs and imprisonment, any of which could adversely affect the Company's ability to market its products and materially adversely affect the Company's business, results of operations and financial condition. Any action against the Company for violation of these laws, even if the Company successfully defends against it, could cause the Company to incur significant legal expenses and divert the Company's management's attention from the operation of its business.

## ***Insurance Reimbursement***

### *US Insurance Reimbursement CPT codes*

The American Medical Association (AMA) released six Category III CPT billing codes for Breast CT technology on January 1, 2021. Category III codes represent codes for new and emerging technology, services, and procedures. The AMA issuance of these initial insurance billing codes spotlights dedicated breast CT as a promising emerging technology. It is an important development and step in the reimbursement process and aligns with Izotropic's activities in working with payors to secure future coverage. New Category III codes for CT of the breast have been developed with designations for unilateral/bilateral as well as standard contrast options. These codes are:

- **0633T** Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material



- **0634T** Computed tomography, breast, including 3D rendering, when performed, unilateral; with contrast material(s)
- **0635T** Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast, followed by contrast material(s)
- **0636T** Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)
- **0637T** Computed tomography, breast, including 3D rendering, when performed, bilateral; with contrast material(s)
- **0638T** Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast, followed by contrast material(s)

#### *Re-imbursement Activities*

On March 24, 2021, the Company partnered with EXCITE International, a global network of payors, health systems, patients, scientists, and end-users, to prepare for future commercial adoption of IzoView. This partnership complements the Company's engagement with the FDA's Center for Devices & Radiological Health Payor Communication Task Force. Izotropic continues work with EXCITE's network to align the device, clinical trial design, and regulatory strategy with potential payor groups, methodologists, and expert end-users. Izotropic is integrating all inputs from various groups within the aforementioned sectors to increase the potential breadth and speed of adoption of IzoView upon regulatory approval.

#### ***Breast Cancer Facts and Statistics***

In 2020, 2.3 million cases of breast cancer are diagnosed globally, and approximately 685,000 women die from the disease each year, according to the World Health Organization. According to the American Cancer Society, more than 281,500 new cases of invasive breast cancer will have been diagnosed in women in 2021 in the U.S., and over 43,000 American women will die from this disease. Early detection is the key to reducing the chance that a woman who is diagnosed with breast cancer will die from the disease. Breast tumors detected early are smaller and typically have not metastasized to other regions of the body, which is a key factor in improving survival.

While much research focuses on breast cancer prevention, no major advancements in early detection have been made in many years. Two-view mammography is the current standard of care for breast cancer screening, and approximately 39 million women undergo mammography screening each year in the U.S., according to the FDA's Mammography Quality Standards Act (the "MQSA") and Program. While digital mammography is commonly used for breast cancer screening in the U.S. and other developed nations, similar technology called tomosynthesis (technically, limited-angle tomography) is also being used to improve cancer detection, either alone or with mammography. Despite the success of mammography in driving down breast cancer mortality since its widespread introduction in the late 1980s, screening mammography is not an ideal test for the following reasons:

- it misses approximately one in five breast cancers, according to the webpage "Mammograms" on the National Cancer Institute website;
- it commonly produces false positive results, a mammogram that looks irregular when no cancer is present, as about 50 percent of women who get annual mammograms over a 10-year period in the U.S. will have a false-positive finding at least once, according to the webpage "Mammograms" on the National Cancer Institute website; and
- it requires breast compression and technologist handling of the patient's breast, which may be painful to the patient, according to "Breast Imaging: The Requisites E-Book, 3rd Edition".

For these reasons, the Company believes the breast imaging community may benefit from a cost-effective, true 3D breast imaging technology that improves patient comfort and delivers high diagnostic accuracy.

### ***Market Outlook***

In the short term, the Company's management expects breast CT to likely emerge as an important tool for diagnostic breast examinations, which are performed following a concerning mammogram or when the presence of a tumor is suspected. Longer term, the Company's management expects breast CT to partially or completely replace mammography for breast cancer screening. It also believes breast CT will become a platform for biopsy, surgical planning, treatment and therapy in future.

### ***Market Sizing***

- There are over 6,000 hospitals with imaging centers and 2,500 imaging clinics in the U.S.
- There are over 23,000 certified mammography and tomosynthesis units installed at these hospitals and clinics

The MQSA became law in the U.S. in October 1992. U.S. Congress enacted MQSA to ensure that all patients have access to quality mammography for the detection of breast cancer in its earliest, most treatable stages. On October 1, 2021, MQSA reported over 8,500 certified facilities having over 23,000 digital mammography and/or digital tomosynthesis units. These units conducted over 38M mammography procedures reported in 2020-2021. Despite the challenges with COVID (October 2020 – October 2021) and significant well-known decrease in patients getting breast imaging, there was a 0.5% increase in MQSA accredited imaging facilities and a 6.4% increase in digital mammography and tomosynthesis accredited units at these facilities. This suggests the breast imaging equipment market in the U.S. remains strong.

Two larger market trends may also contribute to market demand:

- Breast cancer has surpassed lung cancer and is now the most common cancer globally. The worldwide population is aging—and breast cancer incidence increases with age. According to “An Aging World: 2015”, a study commissioned by the U.S.’ National Institutes on Health and produced by the U.S. Census Bureau, in 2015, 8.5 percent of the world population was age 65 or older. By 2050, that percentage is projected to increase to 17 percent, according to the study.
- Healthcare costs are also rising, causing increasing concern for governments, insurers, and patients.

This combination of an aging population and rising healthcare costs may lead to increased demand and utilization of cost-effective, accurate, early cancer detection and prevention technologies. Next-generation imaging technologies such as IzoView breast CT, that help to lower costs through more accurate early detection, with reduced false-positive imaging tests and fewer unnecessary biopsies, could be increasingly adopted.

As articulated on our Company's website under management (<https://izocorp.com/investors/management/>) and advisors (<https://izocorp.com/investors/advisors/>) the Company has engaged an experienced CEO with executive level background in medical imaging companies, a strong slate of industry advisors, and an executive level engineering manager and also supervises the medical imaging device engineering and manufacturing external resources engaged to assist in designing and manufacturing IzoView prototype and clinical study units.

### ***Production and Services***

The Company has engaged an experienced CEO with executive level background in medical imaging companies and an executive level engineering manager that also supervises the medical imaging device engineering and manufacturing company, Starfish Medical.

### ***Specialized Skill and Knowledge***

As above, the Company has qualified management and has had no difficulty recruiting, or engaging, necessary expertise to drive its business objectives.

### ***Competitive Condition***

There is significant competition for breast imaging technology for early diagnosis of breast cancer, as well as for hiring qualified personnel in the breast imaging market. The Company's competitors may have more substantial financial and technical resources for breast imaging technology for early diagnosis of breast cancer, as well as for the recruitment and retention of qualified personnel. The Company faces competition from established providers of existing breast imaging technology. In addition, researchers around the world are working on new breast imaging technologies and refinements to current offerings. See "Risk Factors".

Please see the "Technical Performance Comparison Table" for information and comparison of breast imaging modalities.

### ***New Products***

The Company is currently focussed solely on Breast CT as an imaging device and does not have any new products.

### ***Components***

Izotropic has identified one or more suppliers for key components of the IzoView system to create a robust supply chain. For other components with limited number of suppliers or unique technology, Izotropic's engineering team intends to modify available components where possible for the initial prototype and clinical study units. Due to the COVID-19 pandemic, there are well known global supply chain issues which the Company expects to be resolved when IzoView has market authorization to sell products in the U.S.

### ***Intangible Properties***

See section entitled "Licensed Patent Rights" for updated information.

### ***Cycles***

The Company's business and operations are not affected by seasonality.

### ***Economic Dependence***

Aside from the engineering and development of the clinical study units planned for the FDA clinical study, the Company has no contracts that would affect its business at this time.

### ***Changes to Contracts***

See section entitled "The License Agreement" for updated information.

### ***Environmental Protection***

The Company complies with all applicable relevant governmental regulations.

### ***Employees***

As the date of this AIF, the Company has no employees. The Company's executive officers are independent contractors of the Company.

### ***Foreign Operations***

The Company is engaged in partnership with UC Davis. John Boone, a director of the Company, is a professor at UC Davis. For additional details regarding the Company's operations with UC Davis, see the sections entitled "*History of the Izotropic Breast CT Imaging System*", "*Clinical Data*", "*The Commercial Unit*", and "*Risk Factors*".

### ***Lending***

The Company's operations generally do not include any lending operations.

### ***Bankruptcy and Similar Procedures***

There were no bankruptcy, receivership or similar proceedings involving the Company or its subsidiaries, or any voluntary bankruptcy, receivership or similar proceedings by the Company or its subsidiaries, within the three most recently completed financial years, or during or proposed for the current financial year.

### ***Reorganizations***

The Company, including its subsidiary, has not completed any material reorganizations in the previous three completed financial years.

### ***Social or Environmental Policies***

The company adheres to the guidance documentation and recommendations of the FDA and other relevant a organizations and standards.

## **5.2 Risk Factors**

Investors should carefully consider the risks set out below and other information contained in or incorporated by reference in this AIF, including those risks contained in the AIF under the heading "*Risk Factors*". The operations of the Company are highly speculative and notably involve risks inherent to the Company's capacity to successfully implement its solutions with the customers it is currently servicing and its ability to market such solutions. The risks and uncertainties set out below and the additional risks and uncertainties incorporated by reference herein are not the only ones facing the Company. Additional risks and uncertainties not currently known to the Company, or that the Company currently deems immaterial, may also impair the Company's operations. If any of the risks actually occur, the Company's business, operating results and financial condition. As a result, the trading price of the Common Shares could decline and investors could lose part or all of their investment. The Company's business is subject to significant risks and past performance is no guarantee of future performance.

### **Risks Relating to the Company's Business**

#### **Negative Cash Flow from Operating Activities**

The Company has no history of earnings and had negative cash flow from operating activities since inception. To date, the Company has not received and revenues from the sales of IzoView. The Company has accumulated net losses and expects to continue to incur such losses until such time as milestone payments from collaborative partners, licensing fees, product sales or royalty payments generate sufficient revenues to fund its continuing operations.

The Company's ability to attain profitability will depend on a number of factors, some of which are outside its control. These factors include the following:

- its ability to obtain necessary government and regulatory approvals, including FDA market authorization;
- its ability to successfully complete the design and development of the Commercial Unit;

- its ability to successfully commercialize IzoView;
- its ability to protect the intellectual property granted to the Company under the License Agreement;
- the success of its sales and marketing efforts;
- its ability to maintain its competitive advantages;
- new developments in the area of cancer detections and the efficacy of competing technologies;
- market acceptance of its products and services;
- its ability to raise additional capital as and when needed and on acceptable terms;
- the effect of the COVID -19 pandemic on R&D teams, manufacturing, supply chain, clinical study operations; and
- recruitment ability of clinical study sites, cancer positivity rates at each site.

### **No Production History**

The Company has no product sales history and its ultimate success will depend on its operating ability to generate cash flow from sales of its products and services in the future. The Company has not generated any revenue to date and there is no assurance that it will do so in the future.

The Company's business operations are at an early stage of development and its success will be largely dependent upon the outcome of its ultimate strategy of successfully developing and marketing IzoView.

### **The ability of the Company to satisfy the terms of the License Agreement and maintain the License in good standing**

The Company has been granted an exclusive license to the Inventions pursuant to the License Agreement. The Company's rights and obligations are outlined in the License Agreement. The License Agreement requires the Company to complete the License Agreement Milestones. Failure to complete the License Agreement Milestones could allow the Licensor to terminate the License Agreement. The License Agreement may also be terminated by the Licensor if certain other conditions occur. If the Company's relationship with the Licensor were to terminate, the Company would not be able to distribute and commercialize IzoView and might not be able to enter into another license agreement with an entity with similar technologies on acceptable terms or at all. As a result, the Company could experience delays in its ability to distribute and commercialize IzoView or a similar technology, all of which would have a material adverse effect on the Company's business, results of operations and financial condition.

### **The ability of the Company to complete the design and development of the Commercial Unit, as well as create a physical prototype of the Commercial Unit**

Recently, the Company ended its partnership with Starfish Medical but continues to work researchers at UC Davis and third-party engineers at an established development facility in the US which was completed in August of 2022. As of the date of this AIF, the Company's engineers and third-party engineers continue to design, develop and assemble the initial iteration and prototype of the future Commercial Unit. The Company expects the prototype unit to be completed in Q4 of 2022, but there are no assurances the prototype will be completed by this date.

Upon completion of the manufacturing of the initial prototype unit, electrical testing and certification will be required for the completion of additional units specifically for the clinical study. Regulatory authorities will need to approve the use of these units for the clinical study prior to shipping to the clinical study sites. The Company is also dependant on each clinical trial site to reserve appropriate space and facilitate necessary internal processes to initiate a study at the

institution. The Company anticipates the commencement of the clinical study in first half of 2023, but there are no assurances that the Company will receive the various required approvals for the unit by this date.

If this is the case, the Company could experience delays in its ability to begin the clinical study and hence delay the commercialize launch of IzoView, all of which could have a material adverse effect on the Company's business, results of operations and financial condition.

#### **The Company's ability to timely obtain regulatory approvals, including FDA approval, in order to satisfy the terms of the License Agreement**

Under the revised License Agreement, Izotropic has until January 2027 to submit application the FDA, obtain FDA or foreign agency approval, and achieve first commercial sale of IzoView.

The FDA might not approve market authorization the Commercial Unit or might delay approval. As a result, the Company could experience delays in its ability to distribute and commercialize IzoView, all of which would have a material adverse effect on the Company's business, results of operations and financial condition.

The Company's products and operations are subject to extensive regulation in the U.S. by the FDA. The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution and post market support and reporting of medical devices in the U.S. to ensure that medical products distributed in the U.S. are safe and effective for their intended uses. In order to market certain products for use in the U.S., the Company generally must first obtain clearance from the FDA pursuant to the Federal Food, Drug and Cosmetic Act (previously defined as the "FDCA").

To be able to provide the Company's products in other countries, the Company must obtain regulatory market authorization and comply with the regulations of those countries which may differ substantially from those of the U.S. These regulations, including the requirements for market authorization and the time required for regulatory review, vary from country to country. Obtaining and maintaining foreign regulatory approvals is complex, and the Company cannot be certain that it will receive regulatory approvals in any foreign country in which the Company plans to market the Company's products, or to obtain such approvals on a favorable schedule. If the Company fails to obtain or maintain regulatory approval in any foreign country in which the Company plans to market the Company's products, the Company's ability to generate revenue will be harmed.

#### **Additional Requirements for Capital**

Substantial additional financing may be required if the Company is to be successful in pursuing its ultimate strategy of successfully developing and marketing IzoView. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future operations. Revenues, taxes, costs, capital expenditures, operating expenses, regulatory approvals, and the political environment are all factors which will have an impact on the amount of additional capital that may be required. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. There is no assurance that additional financing will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations or anticipated expansion, incur financial penalties, or reduce or terminate its operations.

#### **The Company's ability to timely enter into leasing agreements with hospitals and clinics to lease IzoView**

Neither the Company nor Izotropic Imaging Corp. has entered into any revenue generating agreements with hospitals or clinics for IzoView. The Company's success will be largely dependent upon the outcome of its strategy of successfully developing and marketing IzoView and entering into revenue generating agreements with hospitals and clinics once it has obtained necessary regulatory approvals.

## **Competition**

The Company competes with numerous other research-based imaging companies and organizations that develop, manufacture, market, and sell proprietary imaging technologies, solutions, and products that may possess greater financial resources and technical facilities than the Company in proprietary diagnostic and imaging products for breast cancer, as well as the recruitment and retention of suitably qualified individuals. These competitors may introduce new products or develop technological advances that compete with the Company. The Company cannot predict the timing or impact of competitors introducing new products or technological advances. Such competing products may be safer, more effective, more effectively marketed or sold, or have lower prices or superior performance features than the Company's products, and this could negatively impact the Company's business and results of operations.

## **Laws and regulations affecting government benefit programs could impose new obligations on the Company, require it to change its business practices, and restrict its operations in the future**

The healthcare industry is subject to various federal, state and international laws and regulations pertaining to government benefit programs reimbursement, rebates, price reporting and regulation, and healthcare fraud and abuse. Violations of these laws may be punishable by criminal and/or civil sanctions, including, in some instances, substantial fines, imprisonment, and exclusion from participation in federal and state healthcare programs. These laws and regulations are broad in scope and they are subject to change and evolving interpretations, which could require the Company to incur substantial costs associated with compliance, or to alter one or more of its sales or marketing practices. In addition, violations of these laws, or allegations of such violations, could disrupt the Company's business and result in a material adverse effect on its business and results of operations.

## **The international nature of the Company's business subjects it to additional business risks that may cause its revenue and profitability to decline**

The Company's business is subject to risks associated with doing business internationally, including in emerging markets. As the Company's market is global, the Company faces risks that may include:

- Fluctuations in currency exchange rates;
- Multiple legal and regulatory requirements that are subject to change and that could restrict the Company's ability to manufacture, market, and sell its products;
- Trade-protection measures and import or export licensing requirements;
- Difficulty in establishing staffing and managing operations;
- Differing labour regulations;
- Inflation, recession, and fluctuations in interest rates;
- Political and economic instability; and
- Price and currency exchange controls, limitations on participation in local enterprises, expropriation, nationalization, and other governmental action.

The aforementioned risks may have a material adverse effect on the Company's revenues and profitability.

## **Technological change**

The digital imaging industry is susceptible to technological advances and the introduction of new products utilizing new technologies. Further, the digital imaging industry is also subject to changing industry standards, market trends and customer preferences, and to competitive pressures which can, among other things, necessitate revisions in

pricing strategies, price reductions and reduced profit margins. The Company's success will depend on its ability to secure technological superiority in its products and maintain such superiority in the face of new products. While the Company believes that its products will be competitive, no assurances can be given that the Company's products will be commercially viable or that further modification or additional products will not be required to meet demands or to make changes necessitated by competitors' developments that might render the Company's products less competitive, less marketable, or even obsolete over time.

### **Management of growth**

The Company may be subject to growth-related risks, including capacity constraints and pressure on its internal systems and controls. The Company's ability to manage its growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train, and manage its employee base. Inability of the Company to deal with this growth could have a material adverse impact on its business, operations, and prospects.

### **Protection of intellectual property**

Although the Company does not believe that its products infringe on the proprietary rights of any third parties, there can be no assurance that infringement or invalidity claims (or claims for indemnification resulting from infringement claims) will not be asserted or prosecuted against the Company or the Licensor or that any such assertions or prosecutions will not materially adversely affect the Company's business, financial condition, or results of operations. Regardless of the validity or the successful assertion of such claims, the Company could incur significant costs and diversion of resources with respect to the defense thereof, which could have a material adverse effect on the Company's business, financial condition, or results of operations. The Company's performance and ability to compete are dependent to a significant degree on the proprietary technology licensed to it under the License Agreement. The Company relies on the patents and a combination of copyright and trade secret laws, as well as confidentiality agreements and technical measures, to establish and protect the proprietary rights of the Inventions. As part of its confidentiality procedures, the Company generally enters into agreements with its employees and consultants and limits access to and distribution of its documentation and other proprietary information.

Accordingly, while the Company will endeavor to protect the intellectual property licensed to it under the License Agreement, there can be no assurance that the steps taken by the Company will prevent misappropriation of that technology or that agreements entered into for that purpose will be enforceable. The laws of other countries may afford the Company little or no effective protection of its intellectual property or the intellectual property of the Licensor.

### **Product Liability Claims**

The Company may become subject to liability in connection with the use of IzoView, such as unusual litigation claims that cannot be insured against or against which it may elect not to be so insured because of high premium costs or other reasons. The Company has agreed to indemnify the Licensor under the License Agreement with respect to certain types of claims. However, the Company may incur a liability to third parties (in excess of any insurance coverage) arising from damage or injury.

### **Risks Relating to the Company's Management**

#### **Conflicts of Interest**

The Company's directors and officers may act as directors and/or officers of other companies engaged in the development of diagnostic products for the early detection of breast cancer. As such, the Company's directors and officers may be faced with conflicts of interests when evaluating alternative opportunities. In addition, the Company's directors and officers may prioritize the business affairs of another Company over the affairs of the Company.



## **The Company's future performance is dependent on its management team**

The Company has a small management team and the loss of any key individual could affect the Company's business. Any inability to secure and/or retain appropriate personnel may have a materially adverse impact on the business and operations of the Company.

## **Risks Relating to the Company's Common Shares**

### **Substantial number of authorized but unissued Common Shares**

The Company has an unlimited number of Common Shares that may be issued by the Board without further action or approval of the Company's shareholders. While the Board is required to fulfill its fiduciary obligations in connection with the issuance of such Shares, the Shares may be issued in transactions with which not all shareholders agree, and the issuance of such Shares will cause dilution to the ownership interests of the Company's shareholders.

### **Dilution**

The financial risk of the Company's future activities will be borne to a significant degree by purchasers of the Common Shares. If the Company issues Common Shares from its treasury for financing purposes, control of the Company may change and purchasers may suffer additional dilution.

### **Liquidity of the Common Shares**

Having listings on public stock exchanges should not be taken as implying that there will be a liquid market for the Common Shares. Thus, an investment in the Common Shares may be difficult to realize. Investors should be aware that the value of the Common Shares may be volatile. Investors may, on disposing of Common Shares, realize less than their original investment, or may lose their entire investment. The Common Shares, therefore, may not be suitable as a short-term investment.

The market price of the Common Shares may not reflect the underlying value of the Company's net assets. The price at which the Common Shares will be traded, and the price at which investors may realize their Common Shares, will be influenced by a large number of factors, some specific to the Company and its proposed operations, and some which may affect the sectors in which the Company operates. Such factors could include the performance of the Company's operations, large purchases or sales of the Common Shares, liquidity or the absence of liquidity in the Common Shares, legislative or regulatory changes relating to the business of the Company, and general market and economic conditions.

### **Volatility of the Common Shares**

The share price of publicly traded smaller companies can be highly volatile. The value of the Common Shares may go down as well as up and, in particular, the share price may be subject to sudden and large falls in value given the restricted marketability of the Common Shares.

### **Current market volatility**

The securities markets in the U.S. and Canada may experience price and volume volatility, and the market prices of securities of many companies may experience wide fluctuations in price which have not necessarily been related to the operating performance, underlying asset values or prospects of such companies. There can be no assurance that continual fluctuations in price will not occur. It may be anticipated that any market for the Common Shares will be subject to market trends generally, notwithstanding any potential success of the Company. The value of the Common Shares distributed hereunder will be affected by such volatility.

## **Tax issues**

Income tax consequences in relation to the securities offered will vary according to the circumstances of each purchaser. Prospective purchasers should seek independent advice from their own tax and legal advisers prior to subscribing for the securities.

## **General**

Although management believes that the above risks fairly and comprehensively illustrate all material risks facing the Company, the risks noted above do not necessarily comprise all those potentially faced by the Company as it is impossible to foresee all possible risks.

Although the Board will seek to minimize the impact of the risk factors, an investment in the Company should only be made by investors able to sustain a total loss of their investment. Investors are strongly recommended to consult a person who specializes in investments of this nature before making any decision to invest.

## **PART 6 DIVIDENDS AND DISTRIBUTIONS**

The Company has not declared any cash dividends on its Shares since its inception and intends to retain its earnings to finance growth and expand its operations. It does not anticipate paying any dividends on its Shares or on any other classes of its securities in the foreseeable future.

Under the CBCA, the Company may declare or pay a dividend in property, including in money, unless there are reasonable grounds for believing that the Company is insolvent, or the payment of the dividend would render the Company insolvent.

## **PART 7 DESCRIPTION OF CAPITAL STRUCTURE**

### **7.1 Common Shares**

The authorized capital of the Company consists of an unlimited number of Shares without par value and without special rights and restrictions. As at November 3, 2022, 49,355,021 Shares were issued and outstanding.

The holders of the Common Shares are entitled to receive notice of and to attend and vote at all meetings of the shareholders of the Company and each Common Share confers the right to one vote in person or by proxy at all meetings of the shareholders of the Company. The holders of the Common Shares, subject to the prior rights, if any, of any other class of Shares of the Company, are entitled to receive such dividends in any financial year as the Board may by resolution determine. In the event of the liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of the Common Shares are entitled to receive, subject to the prior rights, if any, of the holders of any other class of Shares of the Company, the remaining property and assets of the Company. The Common Shares do not carry any pre-emptive, subscription, redemption or conversion rights, nor do they contain any sinking or purchase fund provisions.

### **7.2 Constraints**

There are no constraints on the ownership of securities of the Company.

### **7.3 Ratings**

Neither the Company, nor any of its subsidiaries, has received any ratings.

## PART 8 MARKET FOR SECURITIES

### 8.1 Trading Price and Volume

The Shares have been listed on the CSE under the trading symbol “IZO” since June 4, 2018. The following table sets forth the reported intraday high and low prices and the trading volume for the Shares on the CSE, as applicable, on a monthly basis for each month of the financial year ended April 30, 2022 and to the date of this AIF:

Month	High (\$)	Low (\$)	Volume Traded
November 1, 2022 to November 2, 2022	0.65	0.55	68,707
October 2022	0.66	0.375	865,454
September 2022	0.64	0.43	438,691
August 2022	0.71	0.405	920,069
July 2022	0.43	0.35	356,921
June 2022	0.60	0.285	1,066,757
May 2022	0.70	0.485	931,379
April 2022	0.73	0.64	713,849
March 2022	0.73	0.59	865,447
February 2022	0.78	0.67	674,375
January 2022	0.95	0.71	864,345
December 2021	1.08	0.87	518,217
November 2021	1.13	0.85	1,237,783
October 2021	1.24	0.85	2,908,946
September 2021	0.98	0.72	1,214,957
August 2021	0.77	0.66	845,299
July 2021	0.84	0.67	858,002
June 2021	0.99	0.70	1,959,775
May 2021	1.25	0.87	1,879,068

### 8.2 Prior Sales

Except as disclosed in the table below, during the year ended April 30, 2022 and to the date of this AIF, the Company did not issue any class of securities other than Shares.

Security	Date of Issuance	Number of Securities	Exercise Price per Security (\$)	Expiry Date
Options <sup>(1)</sup>	June 30, 2021	450,000	0.74	June 30, 2023
Options <sup>(2)</sup>	March 11, 2022	100,000	0.65	March 10, 2027
Warrants <sup>(3)</sup>	April 1, 2022	826,613	0.62	March 31, 2023
Options <sup>(4)</sup>	April 18, 2022	200,000	0.65	April 18, 2023
Options <sup>(5)</sup>	November 1, 2022	2,160,000	0.61	October 31, 2025

- (1) Options issued to a consultant, all of which vested on the date of grant.
- (2) Options issued to a consultant, an advisor and an executive of the Company, all of which vested on the date of grant.
- (3) Issued in connection with the non-brokered private placement of the Notes.
- (4) Options issued to a consultant. The Options vested as follows: (i) 50% on May 18, 2022; and (ii) 50% on July 17, 2022.
- (5) Options issued to a consultants, advisors and a director of the Company, all of which vested on the date of grant.

## **PART 9 ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER**

As of the date of this AIF, the Company does not have any securities subject to escrow or contractual restriction on transfer.

## **PART 10 DIRECTORS AND EXECUTIVE OFFICERS**

### **10.1 Name, Occupation and Security Holding**

The table below sets out certain information regarding the directors and executive officers of the Company as at the date of this AIF. The directors of the Company are elected at each annual general meeting and hold office until the next annual general meeting, or until their successors are duly elected or appointed in accordance with the Company's articles or until such director's earlier death, resignation or removal.

<b>Name Province/State Country of Residence and Position(s) with the Company<sup>(1)</sup></b>	<b>Principal Occupation during past Five Years</b>	<b>Periods during which Director or Executive Officer has Served</b>	<b>Number and Percentage of Common Shares Owned, or Controlled or Directed<sup>(2)</sup></b>
Robert Thast British Columbia, Canada <i>Director</i>	Mr. Thast has served as a director of the Company since May 19, 2016. He was the CEO and President of the Company from May 19, 2016 to April 5, 2021 and the Secretary from May 19, 2016 to August 25, 2020.	May 19, 2016 to Present	3,866,667 (7.8%)
Ali Sodagar <sup>(3)</sup> British Columbia, Canada <i>Director</i>	Mr. Sodagar founded Sodagar & Company Law Corp. in 2006, a multidiscipline law firm specializing in international business transactions, project finance, mergers and acquisition, corporate, real estate and intellectual property. Mr. Sodagar's main areas of practice are: business, corporate & commercial law, civil litigation and intellectual property.	May 22, 2017 to Present	429,000 <sup>(4)</sup> (0.87%)
John McGraw Ontario, Canada <i>CEO and Director</i>	Dr. McGraw serves as CEO and Director of the Company. Previously Dr. McGraw was a senior executive at CML HealthCare (TSX: CLC) and Novadaq (NASDAQ: NVDQ) a diagnostic services provider and a medical imaging device company respectively, when they were acquired. He has had extensive experience in medical device therapeutic drug development and healthcare services as an executive and management consultant.	April 5, 2021 to Present (CEO) October 2, 2021 to present (Director)	400,000 <sup>(5)</sup> (0.81%)

Name Province/State Country of Residence and Position(s) with the Company <sup>(1)</sup>	Principal Occupation during past Five Years	Periods during which Director or Executive Officer has Served	Number and Percentage of Common Shares Owned, or Controlled or Directed <sup>(2)</sup>
John Boone <sup>(3)</sup> California, USA <i>Director</i>	Dr. Boone is the principal founder of IzoView breast CT and is a Professor in the Department of Radiology & Department of Biomedical Engineering at UC Davis. He is the Commissioner of the International Commission of Radiation Units & Measurements, Editor- In-Chief of Medical Physics, the official journal of the American Association of Physicists in Medicine, the Co-author of "The Essential Physics of Medical Imaging," the leading textbook for radiology residents, and Recipient of the American Association of Physicists in Medicine, and the recipient of the 2019 William D. Coolidge Gold Medal for the recognition of his lifetime achievement in medical physics.	May 1, 2017	1,000,000 <sup>(6)</sup> (2.03%)
Ralph Proceviat <sup>(3)</sup> British Columbia, Canada <i>Director</i>	Mr. Proceviat has more than 35 years in business, finance, markets and operations spanning several industries operating in Canada, Europe and the U.S. including high tech, software development, manufacturing, telecommunications, real estate and most recently, life sciences. Currently, as Co-founder of the RAMP Executive Consulting Group Inc. ("RAMP") a professional advisory services firm based in Vancouver, BC, Mr. Proceviat provides strategic C-level management and business advisory services to RAMP's clients. Mr. Proceviat is a member of the Chartered Professional Accountants of BC ("CPABC") and holds a Bachelor of Commerce Degree in Management Information Systems from the University of British Columbia.	November 18, 2019	100,000 <sup>(7)</sup> (0.2%)
Jody Bellefleur <i>CFO</i>	Ms. Bellefleur has over 25 years of experience as a corporate accountant, focussing exclusively on public companies for the last 10 years. She is responsible for all aspects of regulatory financial reporting including the preparation of quarterly financial statements, management discussion and analysis reports, the coordination of annual audits, and government tax and regulatory reporting.	July 21, 2018 to present	10,000 <sup>(8)</sup> (0.02%)
Jaclyn Thast <i>Corporate Secretary &amp; Operations Manager</i>	Ms. Thast has 7 years' administrative management experience and has been exclusively focussed on public company operations and compliance for the last 4. In addition to compliance related matters and public company filings, she is responsible for news release drafting and associated research required, board and management communications, accounting, as well as all social media activities, marketing materials and managing promotional initiatives and activates, and coordinating these activities with investor relations consultants.	August 25, 2020 to present	530,000 <sup>(9)</sup> (1.07%)
<b>Total:</b>			<b>6,335,667</b>

- (1) The Company has derived the information with respect to securities ownership from the SEDI profiles of the respective directors and officers as at the date of this AIF.
- (2) Based on 49,355,021 Shares issued and outstanding as of the date of this AIF on an undiluted basis. Such amount does not include securities held by the directors and executives that are convertible or exercisable into Shares.
- (3) Member of the Audit Committee.
- (4) Consists of 419,000 Shares held directly and 10,000 Shares held indirectly through 0900941 B.C. Ltd., a company wholly owned by Ali Sodagar.
- (5) Does not include 200,000 Options exercisable at a price of \$0.20 until January 22, 2025.
- (6) Does not include 400,000 Options exercisable at a price of \$0.61 until October 31, 2025.
- (7) Does not include 100,000 Options exercisable at a price of \$0.37 until February 11, 2025.
- (8) Does not include 100,000 Options exercisable at a price of \$1.08 until February 17, 2023.
- (9) Does not include 300,000 Warrants and 150,000 RSUs.

As of November 3, 2022, the directors and executive officers of the Company beneficially own, or control or direct, directly or indirectly, as a group 6,335,667 Shares representing approximately 12.8% of all outstanding Shares on an undiluted basis.

## **10.2 Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

### ***Corporate Cease Trade Orders***

To the best of management's knowledge, no director or executive officer of the Company is, or within the ten years before the date of this AIF has been, a director, CEO or CFO of any company that:

- (a) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days that was issued while the director or executive officer was acting in the capacity of director, CEO or CFO; or
- (b) was subject to a cease trade order, an order similar to a cease trade order, or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days that was issued after the director or executive officer ceased to be a director, CEO or CFO, and which resulted from an event that occurred while that person was acting in the capacity as director, CEO or CFO.

### ***Bankruptcies***

To the best of management's knowledge, no director or executive officer of the Company or a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company:

- (a) is, as at the date of this AIF, or has been within the ten years before the date of this AIF, a director or executive officer of any company that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets: or
- (b) has, within ten years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of the director, executive officer or shareholder.

### ***Penalties and Sanctions***

To the best of management's knowledge, no director or executive officer of the Company or a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company has been subject to:

- (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or
- (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **10.3 Conflicts of Interest**

The Company may from time to time become involved in transactions which conflict with the interests of the directors and the officers of the Company or the interest of these persons could conflict with those of the Company. Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, in the event that such a conflict of interest arises at a meeting of the directors of the Company, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the directors of the Company are required to act honestly, in good faith and in the best interest of the Company.

## **PART 11 PROMOTERS**

Robert Thast, the Company's Former CEO and current director, took the initiative in the primary organization of the Company and accordingly is a promoter of the Company.

For the number and percentage of each class of voting and equity securities of the Company directly or indirectly held by Mr. Thast, please see the section 10.1 titled "*Directors and Executive Officers – Name, Occupation and Security Holding*".

For a report on the nature and amount of value directly or indirectly received by Mr. Thast, please see the section titled "*Director and NEO Executive Compensation, Excluding Compensation Securities*" and "*Stock Options and Other Compensation Securities*" included in the Management Information Circular dated September 8, 2021 filed on September 9, 2021 on SEDAR which information is incorporated herein by reference. Subsequent to the date of the Management Information Circular, Mr. Thast has received \$265,000.

## **PART 12 LEGAL PROCEEDINGS AND REGULATORY ACTIONS**

### **12.1 Legal Proceedings**

There were no material legal proceedings that the Company is or was a party to, or that any of its property is or was subject of, during the year ended April 30, 2022 and to the date of this AIF.

### **12.2 Regulatory Actions**

There have not been any:

- (a) penalties or sanctions imposed against the Company by a court relating to securities legislation or by a securities regulatory authority during the year ended April 30, 2022 and to the date of this AIF and any other penalties or sanctions imposed by a court or regulatory body against the Company that would likely to be considered important to a reasonable investor in making an investment decision; and
- (b) settlement agreements that the Company entered into before a court relating to securities legislation or with a securities regulatory authority during the year ended April 30, 2022 and to the date of this AIF.

## **PART 13 INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS**

Except for transactions and private placements of securities as disclosed herein, no: (a) director or executive officer of the Company; (b) person or company that beneficially owns, or controls or directs, directly or indirectly, more than

10% of the outstanding Shares; or (c) any associate or affiliate of any of the foregoing, has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or is reasonably expected to materially affect the Company, other than an interest arising solely from the ownership of Shares where such person received no extra or special benefit or advantage not shared on a pro rata basis by all shareholders.

#### **PART 14           TRANSFER AGENTS AND REGISTRARS**

The Company's Registrar and Transfer Agent for its Common Shares is Odyssey Trust Company, located at 323 – 409 Granville Street, Vancouver, BC V6C 1T2.

#### **PART 15           MATERIAL CONTRACTS**

Other than those listed below and those entered into in the ordinary course of the Company's business, there are no material contracts of the Company which were entered into in the most recently completed financial year or which were entered into before the most recently completed financial year but are still in effect as of the date of this AIF.

- Transfer Agent and Registrar agreement dated July 12, 2018 with Odyssey Trust Company;
- License agreement, as more particularly described in the section entitled "*The License Agreement*" in this AIF; and
- Consulting Agreement with StarFish Product Engineering, Inc. dated October 27, 2020 with respect to the development of the Company's IzoView product. From time to time, the parties may execute additional statements of work. Upon execution, unless otherwise expressly agreed, each such additional statement of work shall be deemed to form a part of and be subject to the terms of this consulting agreement.

#### **PART 16           INTERESTS OF EXPERTS**

Dale Matheson Carr-Hilton Labonte LLP, Chartered Professional Accountants, are the Company's auditors and have prepared an opinion with respect to the Company's consolidated financial statements as at and for the year ended April 30, 2022 and the year ended April 30, 2021. Dale Matheson Carr-Hilton Labonte LLP report that they are independent of the Company in accordance with the CPABC Code of Professional Conduct. Izotropic engaged Venable LLP law firm to represent the company in patent development and prosecution. Izotropic has engaged Brooke Consulting, LLC to assist with regulatory matters relating to market authorization in the US.

#### **PART 17           ADDITIONAL INFORMATION**

Additional information relating to the Company may be found on SEDAR at [www.sedar.com](http://www.sedar.com). Additional information including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans are contained in the Company's information circular for the Company's most recent annual meeting of shareholders held on October 8, 2021. The information circular is available on SEDAR at [www.sedar.com](http://www.sedar.com). Additional financial information is provided in the Company's annual audited consolidated financial statements and management's discussion & analysis for the year ended April 30, 2022.

##### **The Audit Committee Charter**

The text of the audit committee charter (the "**Audit Committee Charter**") is attached as Schedule A to this AIF.

##### **Composition of the Audit Committee**

The Company's Audit Committee is currently comprised of three directors, consisting of Ali Sodagar, John Boone and Ralph Proceviat (Chair). Mr. Sodagar, Dr. Boone and Mr. Proceviat are all "independent" as defined in NI 52-110. All of the Audit Committee members are "financially literate", as defined in NI 52-110, as all have the industry experience necessary to understand and analyze financial statements of the Company, as well as the understanding of internal controls and procedures necessary for financial reporting.



The Audit Committee is responsible for review of both interim and annual financial statements for the Company. For the purposes of performing their duties, the members of the Audit Committee have the right at all times, to inspect all the books and financial records of the Company and any subsidiaries and to discuss with management and the external auditors of the Company any accounts, records and matters relating to the financial statements of the Company. The Audit Committee members meet periodically with management and annually with the external auditors.

### **Relevant Education and Experience**

**Ali Sodagar:** Mr. Sodagar founded Sodagar & Company Law Corp. in 2006, a multidiscipline law firm specializing in international business transactions, project finance, mergers and acquisition, corporate, real estate and intellectual property. Mr. Sodagar's main areas of practice are: business, corporate & commercial law, civil litigation and intellectual property.

**John Boone:** Dr. Boone the principal founder of IzoView breast CT and is a Professor in the Department of Radiology & Department of Biomedical Engineering at UC Davis. He is the Commissioner of the International Commission of Radiation Units & Measurements, Editor- In-Chief of Medical Physics, the official journal of the American Association of Physicists in Medicine, the Co-author of "The Essential Physics of Medical Imaging," the leading textbook for radiology residents, and Recipient of the American Association of Physicists in Medicine, and the recipient of the 2019 William D. Coolidge Gold Medal for the recognition of his lifetime achievement in medical physics.

**Ralph Proceviat:** Mr. Proceviat has more than 35 years in business, finance, markets and operations spanning several industries operating in Canada, Europe and the U.S. including high tech, software development, manufacturing, telecommunications, real estate and most recently, life sciences. Currently, as Co-founder of the RAMP, a professional advisory services firm based in Vancouver, BC, Mr. Proceviat provides strategic C-level management and business advisory services to RAMP's clients. Mr. Proceviat is a member of the CPABC and holds a Bachelor of Commerce Degree in Management Information Systems from the University of British Columbia.

### **Reliance on Certain Exemptions**

At no time since incorporation has the Company relied on the exemption provided in section 2.4 of NI 52-110 (De Minimis Non-Audit Services) or an exemption from NI 52-110, in whole or in part, granted under Part 8 (Exemptions). It is not anticipated that the Company will rely on any of the above exemptions.

The Company is relying on the exemption provided by section 6.1 of NI 52-110 which provides that the Company, as a venture issuer, is not required to comply with Part 3 (*Composition of the Audit Committee*) and Part 5 (*Reporting Obligations*) of NI 52-110.

### **Audit Committee Oversight**

At no time since incorporation was a recommendation of the audit committee to nominate or compensate an external auditor not adopted by the Board.

### **Pre-Approval Policies and Procedures**

The audit committee has not adopted specific policies and procedures for the engagement of non-audit services but all such services will be subject to the prior approval of the audit committee. It is not anticipated that the Company will adopt specific policies and procedures.

## External Auditor Service Fees

In the following table, “audit fees” are fees billed by the Company’s external auditor for services provided in auditing the Company’s annual financial statements for the subject year. “Audit-related fees” are fees not included in audit fees that are billed by the auditor for assurance and related services that are reasonably related to the performance of the audit review of the Company’s financial statements. “Tax fees” are fees billed by the auditor for professional services rendered for tax compliance, tax advice and tax planning. “All other fees” are fees billed by the auditor for products and services not included in the foregoing categories.

The aggregate fees billed by the Company’s external auditor during the year ended April 30, 2021 and the year ended April 30, 2022, by category, are as follows:

<b>Financial Year Ended</b>	<b>Audit Fees<sup>(1)</sup></b>	<b>Audit-Related Fees<sup>(2)</sup></b>	<b>Tax Fees<sup>(3)</sup></b>	<b>All Other Fees<sup>(4)</sup></b>
Year Ended April 30, 2022	\$22,207	\$Nil	\$1,500	\$Nil
Year Ended April 30, 2021	\$10,609.80	\$Nil	\$900	\$Nil

(1) “Audit Fees” include fees necessary to perform the annual audit of the Company’s consolidated financial statements. Audit Fees include fees for review of tax provisions and for accounting consultations on matters reflected in the financial statements. Audit Fees also include audit or other attest services required by legislation or regulation, such as comfort letters, consents, reviews of securities filings and statutory audits.

(2) “Audit-Related Fees” include services that are traditionally performed by the auditor. These audit-related services include employee benefit audits, due diligence assistance, accounting consultations on proposed transactions, internal control reviews and audit or attest services not required by legislation or regulation.

(3) “Tax Fees” include fees for all tax services other than those included in “Audit Fees” and “Audit-Related Fees”. This category includes fees for tax compliance, tax planning and tax advice. Tax planning and tax advice includes assistance with tax audits and appeals, tax advice related to mergers and acquisitions, and requests for rulings or technical advice from tax authorities.

(4) “All Other Fees” include all other non-audit services.

## **SCHEDULE "A"**

### **IZOTROPIC CORPORATION (the "Corporation")**

#### **AUDIT COMMITTEE CHARTER**

##### **1. MANDATE**

The audit committee will assist the board of directors of the Corporation (the "**Board**") in fulfilling its financial oversight responsibilities. The committee will review and consider, in consultation with the Corporation's external auditors, the financial reporting process, the system of internal control over financial reporting and the audit process. In performing its duties, the audit committee will maintain effective working relationships with the Board, management and the external auditors. To effectively perform his or her role, each committee member must obtain an understanding of the principal responsibilities of committee membership as well as the Corporation's business, operations and risks.

##### **2. COMPOSITION**

The Board will appoint, from among their membership, an audit committee after each annual meeting of the shareholders of the Corporation. The audit committee will consist of a minimum of three directors.

###### **2.1 Independence**

A majority of the members of the audit committee must be "independent" (as defined in Sec. 1.4 of National Instrument 52-110 (Audit Committees)) ("**NI 52-110**").

###### **2.2 Expertise of Committee Members**

A majority of the members of the audit committee must be "financially literate" (as defined in Sec. 1.6 of NI 52-110) or must become financially literate within a reasonable period of time after their appointment to the committee. At least one member of the committee must have accounting or related financial management expertise.

##### **3. MEETINGS**

The audit committee shall meet in accordance with a schedule established each year by the Board, and at other times that the audit committee may determine. The audit committee shall meet at least annually with the Corporation's CFO and external auditors in separate executive sessions.

##### **4. ROLES AND RESPONSIBILITIES**

The audit committee shall fulfill the following roles and discharge the following responsibilities:

###### **4.1 External Audit**

The audit committee shall be directly responsible for overseeing the work of the external auditors in preparing or issuing the auditor's report, or performing other audit, review or attestation services, including the resolution of disagreements between management and the external auditors regarding financial reporting. In carrying out this duty, the audit committee shall:

- (a) recommend to the Board that the external auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attestation services for the Corporation;
- (b) review (by discussion and enquiry) the external auditors' proposed audit scope and approach;

- (c) review the performance of the external auditors and recommend to the Board the appointment or discharge of the external auditors;
- (d) review and recommend to the Board the compensation to be paid to the external auditors;
- (e) review and confirm the independence of the external auditors by reviewing the non-audit services provided and the external auditors' assertion of their independence in accordance with professional standards; and
- (f) review and approve the Corporation's hiring policies regarding partners and employees, and former partners and employees, of the present and former external auditor of the Corporation.

#### **4.2 Internal Control**

The audit committee shall consider whether adequate controls are in place over annual and interim financial reporting as well as controls over assets, transactions and the creation of obligations, commitments and liabilities of the Corporation. In carrying out this duty, the audit committee shall:

- (a) evaluate the adequacy and effectiveness of management's system of internal controls over the accounting and financial reporting system within the Corporation; and
- (b) ensure that the external auditors discuss with the audit committee any event or matter which suggests the possibility of fraud, illegal acts or deficiencies in internal controls.

#### **4.3 Financial Reporting**

The audit committee shall review the financial statements and financial information of the Corporation prior to their release to the public. In carrying out this duty, the audit committee shall:

##### *General*

- (a) review significant accounting and financial reporting issues, especially complex, unusual and related party transactions;
- (b) review and ensure that the accounting principles selected by management in preparing financial statements are appropriate;

##### *Annual Financial Statements*

- (c) review the draft annual financial statements and provide a recommendation to the Board with respect to the approval of the financial statements;
- (d) meet with management and the external auditors to review the financial statements and the results of the audit, including any difficulties encountered;
- (e) review management's discussion & analysis respecting the annual reporting period prior to its release to the public;

##### *Interim Financial Statements*

- (f) review and approve the interim financial statements prior to their release to the public;
- (g) review management's discussion & analysis respecting the interim reporting period prior to its release to the public; and

#### *Release of Financial Information*

- (h) where reasonably possible, review and approve all public disclosure containing financial information, including news releases, prior to release to the public. An audit committee must be satisfied that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, and must periodically assess the adequacy of those procedures.

#### **4.4 Non-Audit Services**

All non-audit services (being services other than services rendered for the audit and review of the financial statements or services that are normally provided by the external auditor in connection with statutory and regulatory filings or engagements) which are proposed to be provided by the external auditors to the Corporation or any subsidiary of the Corporation shall be subject to the prior approval of the audit committee.

#### *Delegation of Authority*

- (a) The audit committee may delegate to one or more independent members of the audit committee the authority to approve non-audit services, provided any non-audit services approved in this manner must be presented to the audit committee at its next scheduled meeting.

#### *De-Minimis Non-Audit Services*

- (b) The audit committee may satisfy the requirement for the pre-approval of non-audit services if:
  - (i) the aggregate amount of all non-audit services that were not pre-approved is reasonably expected to constitute no more than five per cent of the total amount of fees paid by the Corporation and its subsidiaries to the external auditor during the fiscal year in which the services are provided; or
  - (ii) the services are brought to the attention of the audit committee and approved, prior to the completion of the audit, by the audit committee or by one or more of its members to whom authority to grant such approvals has been delegated.

#### *Pre-Approval Policies and Procedures*

- (c) The audit committee may also satisfy the requirement for the pre-approval of non-audit services by adopting specific policies and procedures for the engagement of non-audit services, if:
  - (i) the pre-approval policies and procedures are detailed as to the particular service;
  - (ii) the audit committee is informed of each non-audit service; and
  - (iii) the procedures do not include delegation of the audit committee's responsibilities to management.

#### **4.5 Other Responsibilities**

The audit committee shall:

- (a) establish procedures for the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls or auditing matters;
- (b) establish procedures for the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters;

- (c) ensure that significant findings and recommendations made by management and the external auditor are received and discussed on a timely basis;
- (d) review the policies and procedures in effect for considering officers' expenses and perquisites;
- (e) perform other oversight functions as requested by the Board; and
- (f) review and update this Charter and receive approval of changes to this Charter from the Board.

#### **4.6 Reporting Responsibilities**

The audit committee shall regularly update the Board about committee activities and make appropriate recommendations.

### **5. RESOURCES AND AUTHORITY OF THE AUDIT COMMITTEE**

The audit committee shall have the resources and the authority appropriate to discharge its responsibilities, including the authority to

- (a) engage independent counsel and other advisors as it determines necessary to carry out its duties;
- (b) set and pay the compensation for any advisors employed by the audit committee; and
- (c) communicate directly with the internal and external auditors.

### **6. GUIDANCE – ROLES & RESPONSIBILITIES**

The audit committee should consider undertaking the actions described in the following guidance, which is intended to provide the audit committee members with additional guidance on fulfilment of their roles and responsibilities on the committee:

#### **6.1 Internal Control**

- (a) evaluate whether management is setting the goal of high standards by communicating the importance of internal control and ensuring that all individuals possess an understanding of their roles and responsibilities;
- (b) focus on the extent to which external auditors review computer systems and applications, the security of such systems and applications, and the contingency plan for processing financial information in the event of an IT systems breakdown; and
- (c) gain an understanding of whether internal control recommendations made by external auditors have been implemented by management;

#### **6.2 Financial Reporting**

##### *General*

- (a) review significant accounting and reporting issues, including recent professional and regulatory pronouncements, and understand their impact on the financial statements;
- (b) ask management and the external auditors about significant risks and exposures and the plans to minimize such risks; and
- (c) understand industry best practices and the Corporation's adoption of them;

### *Annual Financial Statements*

- (d) review the annual financial statements and determine whether they are complete and consistent with the information known to committee members, and assess whether the financial statements reflect appropriate accounting principles in light of the jurisdictions in which the Corporation reports or trades its shares;
- (e) pay attention to complex and/or unusual transactions such as restructuring charges and derivative disclosures;
- (f) focus on judgmental areas such as those involving valuation of assets and liabilities, including, for example, the accounting for and disclosure of loan losses; warranty, professional liability; litigation reserves; and other commitments and contingencies;
- (g) consider management's handling of proposed audit adjustments identified by the external auditors; and
- (h) ensure that the external auditors communicate all required matters to the committee;

### *Interim Financial Statements*

- (i) be briefed on how management develops and summarizes interim financial information, the extent to which the external auditors review interim financial information;
- (j) meet with management and the auditors, either telephonically or in person, to review the interim financial statements;
- (k) to gain insight into the fairness of the interim statements and disclosures, obtain explanations from management on whether:
  - (i) actual financial results for the quarter or interim period varied significantly from budgeted or projected results;
  - (ii) changes in financial ratios and relationships of various balance sheet and operating statement figures in the interim financial statements are consistent with changes in the Corporation's operations and financing practices;
  - (iii) generally accepted accounting principles have been consistently applied;
  - (iv) there are any actual or proposed changes in accounting or financial reporting practices;
  - (v) there are any significant or unusual events or transactions;
  - (vi) the Corporation's financial and operating controls are functioning effectively;
  - (vii) the Corporation has complied with the terms of loan agreements, security indentures or other financial position or results dependent agreement; and
  - (viii) the interim financial statements contain adequate and appropriate disclosures;

### **6.3 Compliance with Laws and Regulations**

- (a) periodically obtain updates from management regarding compliance with this policy and industry "best practices";

- (b) be satisfied that all regulatory compliance matters have been considered in the preparation of the financial statements; and
- (c) review the findings of any examinations by securities regulatory authorities and stock exchanges; and

**6.4 Other Responsibilities**

- (a) review, with the Corporation's counsel, any legal matters that could have a significant impact on the Corporation's financial statements.