

# IZOTROPIC CORPORATION

## MANAGEMENT'S DISCUSSION AND ANALYSIS PREPARED AS OF SEPTEMBER 28, 2020

### INTRODUCTION

The following management's discussion and analysis ("**MD&A**") is a review of operations, current financial position and outlook for the Company and should be read in conjunction with the Company's condensed interim consolidated financial statements for the three months ended July 31, 2020. Readers are encouraged to review the Company's financial statements in conjunction with this document. The Company prepares its financial statements in accordance with International Financial Reporting Standards ("**IFRS**").

As used in this MD&A and unless otherwise indicated, the terms "we", "us", "our", "Company", and refer to Izotropic Corporation. Unless otherwise specified, all dollar amounts are expressed in Canadian dollars.

This MD&A contains forward-looking statements. Forward-looking statements may also be made in the Company's other reports filed with or furnished to the Canadian securities commissions. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from such statements. The words "aim," "anticipate," "believe," "continue," "could," "expect," "intend," "likely", "may," "optimistic," "plan," "potential", "predict", "should," "would," and other similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance, and therefore you should not put undue reliance upon them. The material assumptions supporting these forward-looking statements include, among other things the Company's ability to:

- obtain any necessary financing on acceptable terms;
- satisfy the terms of the License Agreement and maintain the License in good standing,
- complete the design and development of the Commercial Unit, as well as create a physical prototype of the Commercial Unit,
- timely obtain and maintain important regulatory approvals for the Commercial Unit, including FDA approval or CE mark approval,
- timely secure patents relating to the Licensed Patent Rights,
- timely enter into leasing agreements with hospitals and clinics to lease the Isotropic Breast Imaging System,
- appropriately deal with the possible requirement to undergo the PMA process rather than the much shorter and less capital intensive 510(k) process for FDA approval of the Commercial Unit,
- successfully compete with other research-based imaging companies and organizations that develop proprietary diagnostic and imaging products for breast cancer, and
- follow general economic and financial market conditions.

Some of the factors that may cause actual results to differ materially from those indicated in these statements are found in the section "Risk Factors" in this prospectus.

The forward-looking statements contained in this MD&A reflect our views and assumptions only as of the date of this MD&A. The Company undertakes no obligation to update or revise any forward-looking statements after the date on which the statement is made, except as required by applicable laws, including the securities laws of Canada.

## **ABOUT THE COMPANY**

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

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

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

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

Izotropic is a public company listed on Canadian Securities Exchange in Canada ("IZO"), the OTC market in the USA ("IZOZF"), and the Frankfurt Stock Exchange in Germany ("1R3").

## **CORPORATE ACTIVITIES**

- On May 7, 2020, the Company announced the United States Patent and Trademark Office ("USPTO") has issued U.S. Patent No. 11/913494 entitled "Biopsy Systems for Breast Computed Tomography". The patent covers the use of the Company's dedicated Breast CT Imaging System for robotic guided biopsy, giving physicians the ability to manage and obtain samples of suspicious lesions and tumours for pathology testing.
- On May 13, 2020, the Company announced it has 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.
- On May 20, 2020, the Company appointed Anita Nosratieh, Ph.D. to the Advisory Board.
- On May 25, 2020, the Company announced it has engaged 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 June 1, 2020, the Company announced its intention to extend the term of 300,000 share purchase warrants, originally expiring two years from the date of the Company's listing on the Canadian Securities Exchange. The new proposed expiry date will be October 12, 2022.
- On June 4, 2020, the Company announced it has entered into a consulting agreement with James Berard to provide investor relations and communication services and introduce financial professionals to the Company. The initial term is for six months with a monthly fee of \$4,000. The Company also granted Mr. Berard 100,000 stock options priced at \$0.17 and expiring in two years.

- On July 6, 2020, the Company announced the appointment of John McGraw, Ph.D., as Executive Vice President of Commercial Operations.
- On July 8, 2020, the Company announced it had engaged Dr. Craig Abbey, Ph.D., to develop and present proposed reader study designs to the FDA during the Company’s pre-submission meeting for approval of its Breast CT Imaging System.
- On July 10, 2020, the Company announced that its board of directors has 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 US Food and Drug Administration (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.
- On August 27, 2020, the Company appointed Ms. Jaclyn Thast as Corporate Secretary of the Company.
- On August 31, 2020, the Company announced it had entered into a consulting agreement with MarketSmart Communications Inc. (“MarketSmart”) to help build awareness of the Company’s corporate profile within the investment community. The terms of the agreement are for an initial six months with an option for renewal and a monthly fee of \$8,500. Additionally, the Company issued 300,000 stock options to MarketSmart at an exercise price of \$0.75 for a two-year term. The stock options vest immediately.
- On September 15, 2020, the Company appointed Mr. Alexander Tokman as Strategic Advisor to the Company’s advisory board. The Company granted Mr. Tokman 100,000 stock options at an exercise price of \$0.72 expiring in two years.
- The Company has announced it will hold its Annual General Meeting on October 2, 2020.

### **SELECTED ANNUAL INFORMATION**

	<b>Year ended April 30, 2020 (Audited) (\$)</b>	<b>Year ended April 30, 2019 (Audited) (\$)</b>	<b>Year ended April 30, 2018 (Audited) (\$)</b>
<b>Continuing Operations</b>			
Revenue	nil	nil	nil
General and Administrative Expenses	1,155,842	398,537	730,129
<b>Net Loss</b>	<b>1,155,842</b>	<b>398,537</b>	<b>730,129</b>
Basic and Diluted loss per share	0.05 <sup>(3)</sup>	0.02 <sup>(2)</sup>	0.05 <sup>(1)</sup>

**Notes:**

- (1) Based on 13,691,233 Common Shares issued and outstanding for the year ended April 30, 2018.
- (2) Based on 22,680,882 Common Shares issued and outstanding for the year ended April 30, 2019.
- (3) Based on 25,088,103 Common Shares issued and outstanding for the year ended April 30, 2020.

Statement of Financial Position	As at April 30, 2020 (Audited) (\$)	As at April 30, 2019 (Audited) (\$)	As at April 30, 2018 (Audited) (\$)
Assets			
Current assets	773,950	332,518	478,557
Total Assets	777,211	339,058	491,637
Liabilities	69,992	22,215	83,874
Current liabilities	69,992	22,215	83,874
Total Shareholders' Equity (Deficiency)	707,219	316,843	407,763
Total Liabilities and Shareholders' Equity	777,211	339,058	491,637

## **DISCUSSION OF OPERATIONS**

### **Three Months ended July 31, 2020**

#### *Revenues*

For the three months ended July 31, 2020, the Company did not generate any revenue.

#### *Expenses*

For the three months ended July 31, 2020, the Company recorded expenses of \$448,818.

The Company reported a net loss of \$448,818 during the three months ended July 31, 2020 (July 31, 2019 - \$146,421). The increase in loss compared to the prior year's period is due the increased business activities of the Company.

The main factors that contributed to the increased loss during the three months ended July 31, 2020 were:

- professional fees of \$23,048 (July 31, 2019 - \$2,632);
- investor relations fees of \$37,500 (July 31, 2019 - \$5,000);
- consulting fees of \$246,977 (July 31, 2019 - \$14,308); and
- travel, promotions and meals expenses of \$77,622 (July 31, 2019 - \$50,457).

**During the three months ended July 31, 2020 and up to the date of this report, the Company issued the following shares:**

Subsequent to July 31, 2020, 150,000 stock options priced at \$0.26 and 100,000 stock options priced at \$0.30 were exercised.

**During the year ended April 30, 2020, the Company completed the following financings:**

On May 24, 2019, 550,000 share purchase warrants priced at \$0.10 were exercised for gross proceeds of \$55,000.

On June 4, 2019, 75,000 share purchase warrants priced at \$0.10 were exercised for gross proceeds of \$7,500.

On February 11, 2020, 6,150,000 share purchase warrants were exercised at a price of \$0.20 per share for gross proceeds of \$1,230,000 due to a warrant exercise incentive program that was announced on January 28, 2020, whereby for each warrant exercised before February 7, 2020, the holder will receive one additional common share purchase warrant (an "Incentive Warrant"). Each incentive warrant will entitle the warrant holder to purchase one additional common share at a price of \$0.20 per share for a period of two years from the date of issuance.

### **LIQUIDITY AND CAPITAL RESOURCES**

To build our Company into a leading provider of breast CT imaging technology, we may need to continue to raise capital. As a young growth company, we are cognizant that as at July 31, 2020 we were not capable of sustaining our working capital requirements. In order to reach sustainable business operations, we will continue our plan to achieve the Milestones and a positive return to our shareholders.

#### *Working Capital at July 31, 2020*

	<b>At July 31, 2020</b>	<b>At April 30, 2020</b>
	<b>\$</b>	<b>\$</b>
Current assets	367,204	773,950
Current liabilities	64,465	69,992
Working capital surplus	302,739	703,958

The Company reported working capital surplus of \$302,739 and cash on hand of \$226,455 at July 31, 2020 compared to working capital surplus of \$703,958 and cash on hand of \$613,572 at April 30, 2020.

The Company's future capital requirements will depend upon many factors including, without limitation, which regulatory approval path the Company will select. The Company has limited capital resources and may have to rely upon the sale of equity securities for cash required for development purposes, for additional costs and to fund the administration of the Company. Since the Company does not expect to generate any revenues from operations in the near future, it must continue to rely upon the sales of its equity and debt securities to raise capital, which would result in further dilution to the shareholders. There is no assurance that financing, whether debt or equity, will be available to the Company in the amount required by the Company at any particular time or for any period and that such financing can be obtained on terms satisfactory to the Company or at all. See "Risk Factors".

#### *Cash Flows for the three months ended July 31, 2020*

##### *Cash Flows Used in Operating Activities*

The Company's cash flows used in operating activities for the three months ended July 31, 2020 was \$387,117, compared to the Company's cash flows used in operating activities for the three months ended July 31, 2019 of \$109,683, an increase of \$277,434, primarily due to prepaid promotional expenses and increased expenses in the current year.

##### *Cash Provided by Investing Activities*

The Company did not use or receive any cash for investing activities during the three months ended July 31, 2020 or July 31, 2019.

##### *Cash Provided by Financing Activities*

The Company's cash provided by financing activities for the three months ended July 31, 2020 was \$nil (July 31, 2019 - \$62,500) from the exercise of warrants.

## **LICENSING AGREEMENT**

On April 25, 2017, the Company entered into a licensing agreement with the Regents granting the Company an exclusive worldwide license for the Biopsy Systems for breast computed tomography patent and other related patents.

In consideration for this license, the Company agreed to the following terms:

- cash payment of USD \$10,000 (CDN \$13,971) due within 30 days (paid);
- cash payment of USD \$200,000 due 30 days of the earlier of the following:
  - change of control transaction (“Change of Control”), which means the acquisition, merger, reorganization or other transactions where the Company transfers more than 50% of the voting power of the Company is transferred to a third party; and,
  - licensee financing which means the issuance of debt or equity securities of the Company, in bona fide financing transactions with cumulative proceeds of USD \$3,000,000.
- 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 first 15 commercial sales of all licensed products, in any country;
- 1% royalty of net sales of all licensed services; and
- Reimbursement of \$79,871.80 USD in patent costs incurred prior to agreement effective date, as follows per the license agreement and as amended on February 26, 2020:
  - 1/3 on or before the 1<sup>st</sup> anniversary of agreement effective date, amended to May 12, 2017 (paid).
  - 1/3 on or before the 2<sup>nd</sup> anniversary of agreement effective date, amended to October 25, 2019 (paid).
  - 1/3 on or before the 3<sup>rd</sup> anniversary of agreement effective date, amended to October 25, 2020.

The Company is obligated to further develop, manufacture, and market the licensed products and services to meet market demand (“Milestones”) as follows:

- to submit an application covering a licensed product or licensed services to the U.S. Food and Drug Administration (“FDA”) or equivalent foreign agency by June 30, 2018;
- to obtain FDA or equivalent foreign agency approval by December 31, 2021; and,
- to achieve commercial sale and fill the market demand by June 30, 2022 .

The June 30, 2018 milestone has been extended by mutual agreement with licensor to allow for the inclusion of a new patent application, that is in the process of being filed, that will form part of the commercial unit that will be submitted for FDA approval. On February 26, 2020, the Company announced that it had extended the terms of its licensing agreement and now has until January 2027 to execute on the terms agreed to under the commercialization plan.

If the Company is unable to meet the above Milestones, the Company has the right to extend the target date of any Milestones for 1 year for USD \$10,000. The Company has a further right to extend the target date of any Milestone for an additional 1 year upon a payment of USD \$15,000. Furthermore, three additional 1 year extensions of the above Milestones may be granted upon written agreement by the parties for USD \$20,000 per extension.

## **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no off-balance sheet arrangements.

## **TRANSACTIONS BETWEEN RELATED PARTIES**

Key management includes those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly, including the Company's executive officers and certain members of its Board of Directors.

	<b>July 31, 2020</b>	<b>July 31, 2019</b>
Consulting fees, President and CEO	\$ 30,000	\$ 9,000
Consulting fees, Corporate Secretary	22,500	13,034
Share-based payments, directors and officers	-	11,900
<b>Total</b>	<b>\$ 52,500</b>	<b>\$ 33,934</b>

As at July 31, 2020, included in accounts payable and accrued liabilities is \$10,000 (April 30, 2020: \$10,000) due to the VP Marketing, \$10,000 (April 30, 2020: \$nil) due to the CEO, and \$3,500 (April 30, 2020: \$3,500) due to a director. The amounts are non-interest bearing, unsecured and have no set repayment terms.

## **FINANCIAL INSTRUMENTS**

The Company's financial instruments consist of cash, accounts payable and accrued liabilities. Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest, currency or credit risks arising from these financial instruments. The fair values of these financial instruments approximate their carrying values unless otherwise stated.

### **Disclosure of Outstanding Security Data**

The Company had the following common shares, share purchase warrants, and stock options outstanding as of the following dates:

	<b><u>September 24, 2020</u></b>	<b><u>July 31, 2020</u></b>	<b><u>April 30, 2020</u></b>
Common Shares	30,215,499	29,965,499	29,965,499
Stock Options	3,050,000	2,900,000	2,450,000
Warrants	6,450,000	6,450,000	6,459,500
Fully Diluted Shares	39,715,499	39,315,499	38,874,999

### **Risk Factors**

An investment in the Company is speculative and involves a high degree of risk. Accordingly, prospective investors should carefully consider the specific risk factors set out below, in addition to the other information contained in this document, before making any decision to invest in the Company. The Directors consider the following risks and other factors to be the most significant for potential investors in the Company, but the risks listed do not necessarily comprise all those associated with an investment in the Company and are not set out in any particular order of priority. Additional risks and uncertainties not currently known to the Directors may also have an adverse effect on the Company's business.

If any of the following risks actually occur, the Company's business, financial condition, capital resources, results or future operations could be materially adversely affected. In such a case, the price of the Common Shares could decline and investors may lose all or part of their investment.

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

**We are and may continue to be significantly impacted by the worldwide economic downturn due to the COVID-19 pandemic.**

In December 2019, a novel strain of coronavirus, or COVID-19, was reported to have surfaced in Wuhan, China. COVID-19 has spread to many countries, including the United States and Canada, and was declared to be a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and the U.S., Canada, Europe and Asia have implemented severe travel restrictions and social distancing. The impacts of the outbreak are unknown and rapidly evolving. A widespread health crisis has adversely affected and could continue to affect the global economy, resulting in an economic downturn that could negatively impact the value of the company's shares and investor demand for shares generally.

The continued spread of COVID-19 has also led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. It is possible that the continued spread of COVID-19 could cause a further economic slowdown or recession or cause other unpredictable events, each of which could adversely affect our business, results of operations or financial condition.

The extent to which COVID-19 affects our financial results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 outbreak and the actions to contain the outbreak or treat its impact, among others. Moreover, the COVID-19 outbreak has had and may continue to have indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID-19 or any other pandemic harms the global economy generally.

Within the first quarter of 2020, due to government imposed Shelter In Place Orders, the company is closely monitoring the very fluid situation with respect to COVID-19 such as travel restrictions and the continued closure of the US-Canada border as our development team is based in Canada.

### **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 the Isotropic Breast Imaging System. 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 approval;
- its ability to successfully complete the design and development of the Commercial Unit;
- its ability to successfully commercialize the Isotropic Breast Imaging System;
- its ability to secure the Milestone Patents;
- 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; and
- its ability to raise additional capital as and when needed and on acceptable terms.

### **No Production History**

The Company has no product sales history 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 the Isotropic Breast Imaging System.

### **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 the Isotropic Breast Imaging System 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 the Isotropic Breast Imaging System 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**

The Company, in partnership with researchers at UC Davis and third party engineers, continues to design and develop the Commercial Unit. The Company expects the design and development of the Commercial Unit to be completed by July 2018. There are no assurances that the design and development of the Commercial Unit will be completed by this deadline. As a result, the Company could experience delays in its ability to distribute and commercialize the Isotropic Breast Imaging System, all of which would 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 or CE approval, in order to satisfy the terms of the License Agreement**

Under the License Agreement, the Company is required to 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 and obtain FDA or equivalent foreign agency approval by December 31, 2021 (subsequently extended to 2027 – see "Licensing Agreement"). The FDA might not approve the Commercial Unit, might delay approval, or might require premarket approval (previously defined as "PMA") rather than the less stringent 501(k) approval. If the FDA requires PMA for the Commercial Unit, the Company might seek reclassification of the Commercial Unit by the FDA through the de novo process, might elect to seek CE mark approval in Europe, or extend the deadlines to make a regulatory application and obtain a form of regulatory approval as outlined in the License Agreement Milestones. As a result, the Company could experience delays in its ability to distribute and commercialize the Isotropic Breast Imaging System, all of which would have a material adverse effect on the

Company's business, results of operations and financial condition. The June 30, 2018 milestone has been extended by mutual agreement with Licensor to allow for the inclusion of a new patent application, that is in the process of being filed, that will form part of the commercial unit that will be submitted for FDA approval

The Company's products and operations are subject to extensive regulation in the United States by the U.S. Food and Drug Administration or FDA. The FDA regulates the development, bench and clinical testing, manufacturing, labeling, storage, record keeping, promotion, sales, distribution and postmarket support and reporting of medical devices in the United States to ensure that medical products distributed in the United States are safe and effective for their intended uses. In order for us to market certain products for use in the United States, the Company generally must first obtain clearance from the FDA pursuant to the the Federal Food, Drug and Cosmetic Act (previously defined as the "FDCA"). Clearance under Section 510(k) requires demonstration that a new device is substantially equivalent to another device with 510(k) clearance or grandfathered status. Clearance under the de novo review requires that a new device presents a moderate or low risk.

In addition, if the Company develops products in the future that are not considered to be substantially equivalent to a device with 510(k) clearance or grandfathered status or presenting more than a moderate or low risk, the Company will be required to obtain FDA approval by submitting a PMA. The FDA may not act favorably or quickly in its review of the Company's 510(k), de novo review or PMA submissions, or the Company may encounter significant difficulties and costs in the Company's efforts to obtain FDA clearance or approval, all of which could delay or preclude sale of new products in the United States. Furthermore, the FDA may request additional data or require us to conduct further testing, or compile more data, including clinical data and clinical studies. Regulatory policy affecting the Company's products can change at any time. The changes and their impact on the Company's business cannot be accurately predicted. Changes in the FDA 510(k) or de novo review process could make approval more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on the Company's ability to obtain and maintain approval for the Company's products. The FDA may also, instead of accepting a 510(k) or de novo review submission, require us to submit a PMA, which is typically a much more complex, lengthy and burdensome application. To support a PMA, the FDA would likely require that the Company conduct one or more clinical studies to demonstrate that the device is safe and effective. In some cases such studies may be requested for non-PMA submissions as well. We may not be able to meet the requirements to obtain 510(k) or de novo review clearance or PMA approval, in which case the FDA may not grant any necessary clearances or approvals. In addition, the FDA may place significant limitations upon the intended use of the Company's products as a condition to a 510(k) or de novo review clearance or PMA approval. Product applications can also be denied or withdrawn due to failure to comply with regulatory requirements or the occurrence of unforeseen problems following clearance or approval. Any delays or failure to obtain FDA clearance or approvals of new products the Company develops, any limitations imposed by the FDA on new product use, or the costs of obtaining FDA clearance or approvals could have a material adverse effect on the Company's business, financial condition and results of operations.

To be able to provide the Company's products in other countries, the Company must obtain regulatory approvals and comply with the regulations of those countries which may differ substantially from those of the United States. These regulations, including the requirements for approvals 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.

The EU requires that manufacturers of medical products obtain the right to affix the CE mark to their products before selling them in member countries of the EU. The CE mark is an international symbol of adherence to quality assurance standards and compliance with applicable European medical device directives. In order to obtain the authorization to affix the CE mark to products, a manufacturer must obtain certification that its processes meet certain European quality standards. If the Company is unable to obtain permission to affix the CE mark to the Company's products, the Company will not be able to sell the Company's products in member countries of the EU

and many affiliated countries that accept the CE mark, which would have a material adverse effect on the Company's results of operations. Some member states of the European Union have additional requirements for registration and notification which may add to the time and effort to obtain market access. In addition, the regulations applied to end users of the Company's products may increase over time, forcing us to provide additional solutions to regulations which do not apply directly to us, but which apply indirectly as they may limit the Company's customers' ability to use the Company's products.

### **The Company's ability to successfully secure patents relating to the Licensed Patent Rights**

Under the License Agreement, the Company has agreed to fund the Licensor's applications for the patents under the Licensed Patent Rights. The USPTO might not approve the Milestone Patents or might delay approval. As a result, the Company could experience delays in its ability to distribute and commercialize the Isotropic Breast Imaging System, all of which would have a material adverse effect on the Company's business, results of operations and financial condition.

### **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 the Isotropic Breast Imaging System. 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 the Isotropic Breast Imaging System**

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

### **Use of Funds**

The Company has prepared a detailed budget setting out the way in which it proposes to expend the funds raised under the Offering. However, the quantum and timing of expenditure will necessarily be dependent upon the Company's ultimate strategy of successfully developing and marketing the Isotropic Breast Imaging System. As the Company continues to develop the Isotropic Breast Imaging System, it is possible that circumstances may dictate a departure from the pre-existing budget. Further, the Company may, from time to time as opportunities arise, utilize part of its financial resources (including the funds raised as part of the Offering) to participate in additional opportunities that arise and fit within the Company's broader objectives, as a means of advancing shareholder value.

### **The possible requirement to undergo the PMA process rather than the much shorter and less capital intensive 510(k) process for FDA regulatory approval of the Commercial Unit**

The Company's Commercial Unit may not be approved for the 510(k) FDA process. The PMA pathway is estimated to take up to 24 months at a cost of up to approximately US\$2 million. Since there is a distinct advantage to seeking a PMA, as it is a higher approval process that would facilitate faster approvals outside the United States

and medical insurers in the United States do not dispute costs associated with a technology that has FDA clearance through a PMA, the Company may elect to undertake a PMA approval process instead of a less expensive alternative such as CE mark approval in Europe. In the event the Company elects to undertake a PMA, it may seek an industry partner to fund associated costs in exchange for select marketing rights, or the Company may conduct a financing sufficient to fund PMA when and if elected. The Company may not be able to find an industry partner to fund associated costs for the PMA approval process and may not be able to arrange financing sufficient to fund PMA. As a result, the Company could experience delays in its ability to distribute and commercialize the Isotropic Breast Imaging System, all of which would have a material adverse effect on the Company's business, results of operations and financial condition.

## **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 the Isotropic Breast Imaging System 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 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 Shares**

The Company has an unlimited number of Common Shares that may be issued by the Board of Directors without further action or approval of the Company's shareholders. While the Board of Directors 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.

#### **No Market for Securities**

There is currently no market through which any of the Common Shares, may be sold and there is no assurance that such securities of the Company will be listed for trading on a stock exchange, or if listed, will provide a liquid market for such securities. Until the Common Shares are listed on a stock exchange, holders of the Common Shares may not be able to sell their Common Shares. Even if a listing is obtained, there can be no assurance that an active public market for the Common Shares will develop or be sustained after completion of the Offering. The offering price determined by negotiation between the Company and the Agent was based upon several factors, and may bear no relationship to the price that will prevail in the public market. The holding of Common Shares involves a high degree of risk and should be undertaken only by investors whose financial resources are sufficient to enable them to assume such risks and who have no need for immediate liquidity in their investment. Common Shares should not be purchased by persons who cannot afford the possibility of the loss of their entire investment.

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

Listing on the Exchange 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 United States and Canada have recently experienced a high level of price and volume volatility, and the market prices of securities of many companies have experienced 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 Directors 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.