



**VENTRIPOINT DIAGNOSTICS LTD.**

**MANAGEMENT'S DISCUSSION AND ANALYSIS –  
QUARTERLY HIGHLIGHTS**

**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER  
30, 2022**

## **Introduction**

The following Management's Discussion & Analysis ("MD&A") of Ventripoint Diagnostics Ltd. ("Ventripoint" or the "Company") has been prepared to provide material updates to the business operations, liquidity and capital resources of the Company since its last annual management's discussion & analysis, being the Management's Discussion & Analysis ("Annual MD&A") for the fiscal year ended December 31, 2021. This MD&A does not provide a general update to the Annual MD&A, or reflect any non-material events since the date of the Annual MD&A.

This MD&A has been prepared in compliance with the requirements of section 2.2.1 of Form 51-102F1, in accordance with National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the Annual MD&A, the audited annual consolidated financial statements of the Company for the years ended December 31, 2021, and 2020, and the unaudited condensed consolidated interim financial statements for the three and nine months ended September 30, 2022, together with the notes thereto. Results are reported in Canadian dollars, unless otherwise noted. In the opinion of management, all adjustments (which consist only of normal recurring adjustments) considered necessary for a fair presentation have been included. The results for the three and nine months ended September 30, 2022, are not necessarily indicative of the results that may be expected for any future period. Information contained herein is presented as at November 29, 2022, unless otherwise indicated.

The unaudited condensed consolidated interim financial statements for the three and nine months ended September 30, 2022, have been prepared using accounting policies consistent with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board and interpretations of the IFRS Interpretations Committee. The unaudited condensed consolidated interim financial statements have been prepared in accordance with International Standard 34, Interim Financial Reporting.

The forward-looking statements contained or referenced herein are expressly qualified by this cautionary statement made as of this date. The Company disclaims any intention and has no obligation or responsibility, except as required by law, to update or revise any forward-looking statements.

## **Description of Business**

Ventripoint Diagnostics Ltd. (TSXV:VPT, OTCMKTS:VPTDF), headquartered in Toronto, Canada, is a medical device company engaged in the development and commercialization of diagnostic tools to monitor patients with heart disease – a leading cause of death for both men and women worldwide.

The Company is developing a suite of applications for all major heart diseases and imaging modalities, including congenital heart disease, pulmonary hypertension and cardiotoxicity in oncology patients - a multi-billion-dollar market potential. By using images produced from existing medical imaging systems, the Ventripoint Medical System (VMS™) generates accurate heart volumetric measurements and a three-dimensional model in a rapid and inexpensive manner. Ventripoint's solution produces critical heart information by processing standard information received from existing medical imaging equipment with its patented and proprietary methods incorporating Knowledge Based Reconstruction (KBR) algorithms and proprietary cardiac databases (sometimes called catalogues). The VMS enables medical professionals to economically obtain accurate three-dimensional models from which critical volume and functional

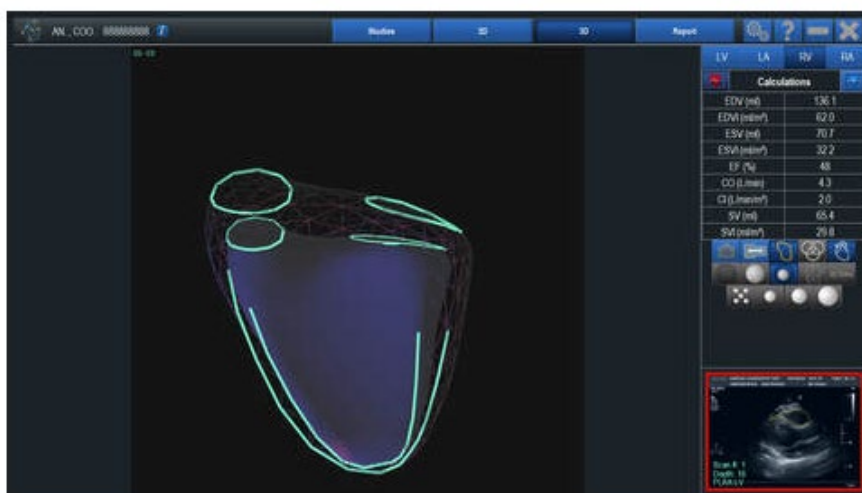
measurements of a patient's heart chambers are derived in only a few minutes more than the time needed for a routine echocardiogram. Measuring volume and function is fundamental in evaluating patients to determine the severity and progression of their disease, assess the effectiveness of treatment, gauge prognosis and decide on the timing of surgical and pharmacological interventions. These key measurements and the 3D model for visual assessment provide medical professionals with some of the critical information necessary for clinical diagnosis and monitoring of their patients.

The Company's KBR method, a form of Artificial Intelligence (AI), allows for the creation of a three-dimensional model of all the chambers of the heart; right and left ventricles, and right and left atria, using images generated from existing 2D and 3D imaging equipment. The Company's technology platform is applicable to all heart diseases. The VMS system is based upon patented and proprietary technology that Ventripoint has licensed on an exclusive basis from the University of Washington. The VMS+3.0 system (hardware and software for 2D echocardiograms) and VMS+3.0 software (software only for 3D echocardiograms and MRI) have US FDA marketing clearance, Health Canada license and European CE Mark for all patients where volumetric information for any of the 4 chambers of the heart is warranted or desired.

Since the commencement of operations, Ventripoint has been committed to commercializing its breakthrough technology to be used as a tool in the diagnosis and management of various heart-related diseases to improve healthcare for these patients worldwide.

It is the Company's goal to have the first system on the mass market that addresses the need for an efficient, accurate and cost-effective heart diagnostic tool that uses standard 2D or 3D echocardiography, as well as MRI images to deliver 3D functional information for all 4 chambers of the heart. The ability to sustain the implementation of its commercialization strategies for its VMS is dependent upon the timely receipt of additional and sufficient operating capital.

### 3D view of Right Ventricle showing End-Systolic and End-Diastolic



## **Outlook and Overall Performance**

### **Strategy**

The Company utilizes both direct sales and distributors in Europe, and the UK and direct sales in USA and Canada and continues to the search for appropriate distributors in all these markets. The Company has a manufacturing and sales partner in China and recently began to explore the South American market through a representative in Brazil (see NR Aug 10, 2022).

The Company believes the support of thought leaders is the first building block for gaining product acceptance and adoption. Accordingly, the Company has collaborated with leading echocardiologists and institutions, in order to establish luminary sites across Canada, the EU and the USA. To build awareness, VMS+3.0 deployments are designed to produce publications in leading medical journals and presentations at conferences. Internationally-ranked hospitals with KOLs have indicated that they will continue the process to acquire a VMS+3.0 once COVID-19 is under control in their region and their hospitals return to normal operations.

To remain competitive, the Company has begun work on the next generation of the VMS+ that will incorporate advanced cardiac measurement features to add further clinical value to the VMS+ products and

For the purposes of preparing this MD&A, management, in conjunction with the Board of Directors, considers the materiality of information. Information is considered material if: (i) such information results in, or would reasonably be expected to result in, a significant change in the market price or value of the Company's common shares; or (ii) there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision; or (iii) it would significantly alter the total mix of information available to investors. Management, in conjunction with the Board of Directors, evaluates materiality with reference to all relevant circumstances, including potential market sensitivity.

Further information about the Company and its operations is available on SEDAR at [www.sedar.com](http://www.sedar.com) and on the Company's website at [www.ventripoint.com](http://www.ventripoint.com).

### **Caution Regarding Forward-Looking Statements**

In the interest of providing current and potential investors in Ventripoint with information regarding the Company's future plans and operations, certain statements and information, which is included or referenced herein, contain "Forward-looking Statements."

Forward-looking Statements include, but are not limited to, statements (collectively, "Statements") with respect to status of technology, development, commercialization, market size, financing, general and administrative, and beyond. You are cautioned not to place undue reliance on forward-looking statements as there can be no assurance that the plans, intentions or expectations they are based on will occur. By their nature, forward-looking statements involve numerous assumptions, known and unknown, and risks and uncertainties, both general and specific, that contribute to the possibility that the predictions, forecasts, projections and other forward-looking statements will not occur.

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Although the Company believes that the expectations represented by such forward-looking statements are reasonable, there can be no assurance that such expectations will prove to be correct. Some of the risks and other factors which could cause results to differ materially from those expressed in the forward-looking statements included or referenced herein include, but are not limited to, access to future funding (debt and/or equity) as described under the section titled "Liquidity"; general economics, business and market conditions as discussed in "Risks and Uncertainties – Financial"; the regulatory approval process as noted in "Risks and Uncertainties – Regulatory"; and the Company's ability to secure additional capital as discussed in "Risks and Uncertainties – Continued Operations". You are cautioned that the foregoing list of important factors is not exhaustive.

With respect to forward-looking statements contained in this MD&A, we have made several key assumptions including, but not limited to:

- the market for the Company's planned product and service offerings is in excess of \$1 billion worldwide and is not subject to decline in the foreseeable future;
- The Company will be able to obtain financing in a timely manner on acceptable terms;
- The current tax and regulatory regimes will remain substantially unchanged;
- The Company will be able to obtain equipment and qualified personnel in a timely manner;
- The Company will successfully market its efficient, accurate and cost-effective heart diagnostic tool that uses standard echo images to deliver functional information about the heart;
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Product and service-related approvals will be obtained from all necessary agencies thereby improving healthcare outcomes. The primary objective of this new proposed product is to provide a complete echo cardiac analysis package with conventional 2D measurements as well as the 3D measurements currently uniquely provided by the VMS+ using 2D or 3D ultrasound. This will provide more quantitative data to clinicians and a visual aid to outline the interrelationships of the heart. These product advances will play a role in helping in the prevention and diagnosis of cardiac disease globally. This is especially relevant today with the need for thorough assessment of cardiac conditions due to COVID-19.

To continue to extend its patent portfolio and thereby strengthen its intellectual property estate, the Company has filed a foundational U.S. provisional patent application for its novel cardiac measurement approach in April 2021. This new measurement technique provides cardiologists with additional and more precise information about the function of the heart through motion tracking. This invention is as an extension of the Company's existing artificial intelligence (AI) platform, which provides accurate and reliable volumetric measurements for all four chambers of the heart. This new technology tracks the movement of heart and valves through the entire heartbeat and not just at the full and empty points in the cardiac cycle. This dynamic information can help in initial diagnosis and assessing the effectiveness of treatments, as well as the timing of interventions thereby improving clinical outcomes. Cardiovascular diseases continue to be the number 1 cause of death worldwide. Constantly advancing the tools available to clinicians for diagnosing and treating patients is key for the future of healthcare.

In August 2021, Ventripoint filed an international patent application under the Patent Cooperation Treaty (PCT) to protect Ventripoint's recent novel improvements to its cardiac measurement technology. Ventripoint is a pioneer in application of artificial intelligence (AI) to heart analysis and this latest application strengthens the company's intellectual property position and coverage for the Ventripoint's flagship products. With this one international patent application, Ventripoint registers its claim to this invention in at least 153 different contracting countries under the PCT. This latest patent application claims a new,

improved method of using 2D and 3D echocardiography data for mapping and displaying the anatomical structure and configuration of the heart. A key novel component is the use of templates with predetermined anatomical landmarks so that multiple anatomical features of the heart are aligned simultaneously. This upgrade to Ventripoint's VMS+ products shortens the analysis time for both 2D and 3D echocardiograms and will help clinicians obtain more accurate and reliable results. The patent relates to the method of using 2D and 3D echocardiography data for mapping and displaying the anatomical structure of the heart for all four pumping chambers of the heart.

In its ongoing efforts to promote the clinical applications for the VMS+ product, the Company has begun publication on the corporate website of case studies and whitepapers showing meritorious use of the VMS Heart Analysis System in routine clinical practice. A series of case studies and white papers will be published to showcase various limitations of current clinical practice, which are overcome by the VMS family of products. Coming topics include user experience perspectives, usability of the VMS products, and VMS use in patients infected with COVID-19.

### **Corporate Highlights**

The Company has made significant progress in implementing its development and commercialization plans. Highlights include:

#### **Collaboration with General Electric Healthcare (GEHC)**

The Company has been seeking marketing and distribution channel partners to build awareness and access to potential customers. The Company recently announced a collaboration with (GEHC). Ventripoint has been added as an innovator under GE Healthcare's Edison Developer Program, which helps healthcare providers gain access to market-ready applications. As an innovator under this program, our installed base will be enhanced and will drive Ventripoint's commercial growth worldwide by accessing GE Healthcare's global channel.

The collaboration between GE Healthcare and Ventripoint offers the potential to enable the medical technology company's global customers to leverage the advanced 3D image analysis tools from the Ventripoint software applications for studies obtained using GE Healthcare's suite of Vivid cardiac ultrasound products.

#### **Collaboration to Expand to Companion Animals**

The Company has initiated a collaboration to expand the use of the VMS+ to include companion animals in January 2021, and is still ongoing.

#### **Quality Management System and Facility Certifications**

In January 2022, The Company successfully completed a surveillance audit of its quality assurance system under Medical Device Directive 93/42/EEC (MDD), Annex II with no findings. This is the first surveillance audit since Ventripoint's last full recertification. The audit by an EU-based Notified Body confirmed that Ventripoint continues to remain in compliance with the requirements of the European Medical Device Directive. Our continued certification allows us to continue to market in CE Mark European countries, which

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include the European Economic Area, Switzerland, and, until 2023, the United Kingdom and until Ventripoint transitions to the new EU Medical Device Regulation (MDR).

In October 2022, The Company successfully completed a factory inspection with no findings. This inspection is part of the 6month inspection cycle carried out by a Nationally Recognized Testing Laboratory (NRTL). The NRTL certificate provides clear evidence that Ventripoint's electrical/electronic products comply with the required standards of the Canadian and U.S. markets.

#### **New Offices and Manufacturing Centre**

The Company has relocated to 18 Hook Avenue, Suite 101 in the “junction” area of Toronto. The new facility is larger than the previous corporate offices and has been configured with a larger manufacturing area and loading/shipping bay. The current manufacturing capacity is 10 units per week capacity with room to grow to 20 units per week. The Company has expanded the manufacturing and QA team in anticipation of increased demand. All employees and contractors have returned to the office four days a week to facilitate coordination and reinforce the innovative culture Ventripoint values so much. The team remains focused and energized around our mission to improve cardiac diagnostics for everyone worldwide and especially for children.

#### **VMS+3.0 Showcased at Medical Conferences**

The Company exhibited at the 71<sup>st</sup> Annual Scientific Session and Expo, hosted by the American College of Cardiology (ACC) between April 2-4, 2022, in Washington, D.C., United States. The ACC is a not-for-profit medical community that has over 54,000 medical professionals worldwide. The ACC aims to provide the best care possible for patients with cardiovascular disease and to help raise awareness about the prevention of cardiovascular disease. The conference highlighted the latest advancements in cardiac care and will be holding specific education sessions for practitioner continuing education. Some of the keynote topics included health equity in cardiovascular disease prevention, technology, heart healthy diet, and more. The conference already has over 18,000 members attending and provided an excellent opportunity for Ventripoint to connect with the cardiovascular community and engage in pressing topics within the field.

In May 2022, the Company sponsored the 2022 SickKids Echo Symposium. The topic of this year's symposium was the introduction to cardiac anatomical (morphological) abnormalities in congenital heart disease, how it relates to echocardiographic imaging, and the use of echocardiographic imaging in surgical decision-making in congenital heart disease. The event had 2000+ attendees and it aims to improve the knowledge of physicians, surgeons, and sonographers who use echocardiograms in newborn and paediatric patient populations or echocardiographic studies in adults with repaired congenital heart disease. This multi-day event will have educational presentations, discussions, and live scanning that focus on the relationship between cardiac morphology and echocardiographic imaging. As a sponsor for the event, Ventripoint's logo was displayed on the conference website and on-screen during scheduled breaks during the weekend courses. There was also an in-person demo of the VMS+, followed by a period for questions about the VMS+ system. This was an excellent opportunity for Ventripoint to educate conference attendees about the capabilities of the VMS+ system, as well as further exposure for those not yet familiar with the system.

Also in May 2022, the Company also sponsored and exhibited at the 55th Annual Meeting of the Association for European Paediatric and Congenital Cardiology (AEPC) held in Geneva, Switzerland between May 25<sup>th</sup>-

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28<sup>th</sup>. The AEPC is a network of specialists in the paediatric and congenital cardiology field who strive to promote the sharing of information and resources within the community. The AEPC is currently one of the largest global associations in the cardiac field with over 1,000 paediatric cardiologists. The conference was hosted by the local organizing committee from the “Centre Universitaire de Cardiologie et Chirurgie Cardiaque Pédiatrique” a collaboration between the University Hospitals of Geneva (HUG) and Vaudois University Hospital Center (CHUV) in Lausanne. The conference focused on the latest advancements in the research and treatment of paediatric and congenital cardiology. Presentation topics included arrhythmia/electrophysiology and basic science, genetics, COVID-19, surgery and preventative care, and many more engaging topics. As a sponsor at the event, Ventripoint's VMS+ system was highlighted in various presentations and in the exhibition space. This meeting presented Ventripoint with an excellent opportunity to engage with the global congenital cardiologist community.

The Company also exhibited at and sponsored the American Society of Echocardiography 33rd Annual Scientific Session (<https://www.asescientificsessions.org/sponsors/>) of the American Society of Echocardiography (ASE) 2022 Conference titled “Sound Waves in Seattle: Connecting the World”. This was the 33rd annual scientific session of the ASE and is being held in the Seattle Convention Center June 10-13, 2022. The ASE is an organization (<https://www.asecho.org/about-ase/>) comprised of members of the cardiac field who work to advance cardiovascular ultrasound and strive to promote education, research, innovation, and service to the profession and public. This year's scientific session brought in thousands of attendees from the cardiovascular profession. Ventripoint was one of the sponsors for the 2022 event and had the opportunity to engage with thousands of attendees through networking sessions, an in-person and virtual exhibit, poster presentations, and hands on educational workshops. Ventripoint joining ASE 2022 through their sponsorship opportunities highlighted the VMS+ and its new developments, allowed the Company to engage with new customers, and establish stronger relationships with existing customers.

In August 2022, The Company exhibited at the 70th European Society of Cardiology (ESC) Congress, which was held in Barcelona, Spain from August 26-29, 2022. The spotlight in 2022 was “Cardiac imaging”, ever more important in cardiovascular medicine with its profound implications from prevention to diagnosis, clinical decisionmaking, guiding of interventions and follow-up of therapeutic procedures. The Congress website (<http://esc2022-congress.org/>) reported 40,000 participants from 170 countries to hear 5,000 medical presentations during the congress. For the first time, the ESC Conference was held virtually and in person, providing access to the latest cardiology research and clinical updates from anywhere in the world. The ESC is comprised of clinicians, scientists, and other professionals in the cardiology field. The ESC aims to unite national cardiac societies from around the world to further study and understand cardiovascular disease. This was yet another opportunity for Ventripoint to inform the cardiology community about its innovative VMS+ products and followed on the heels of the successful AEPC conference this past May in Geneva (see NR May 17, 2022) and the ASE conference in June in Seattle (see NR June 7, 2022). In addition to Ventripoint's direct sales team, our European distributor for Europe, AngioPro, joined us in the exhibition booth to connect with new potential customers and existing users.

In October 2022, The Company hosted an exhibit at the 2022 British Society of Echocardiography Conference in London, England from October 14-15, 2022. Dr. Gregory Skinner, one of Ventripoint's clinical advisors gave a presentation on his experience using the VMS system. This provided excellent exposure for the VMS system and its capabilities for cardiologists and clinicians. This conference further connected Ventripoint to the global echo community and demonstrated how the VMS+ is a reliable and effective cardiac diagnostic tool. Ventripoint's local UK distributor, Cardiologic, also participated in the event. This conference provided valuable networking opportunities for Ventripoint's global partners. This was the tenth



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conference the Company exhibited at in 2022 as it continues to the process of introducing a new diagnostic device to the cardiology community. The British Society of Echocardiography (BSE) is a registered charity that supports clinical echocardiography professionals in order to provide the highest standard of care in echocardiography. BSE was formed in 1990 and has over 4,000 members worldwide. The conference is the BSE's 30th annual conference and has the highest attendance to date. The conference will be attended both in person and virtually, offering a unique hybrid experience

In November 2022, Ventripoint was a gold sponsor and exhibitor of the 2022 Annual Scientific Meeting of the British Congenital Cardiac Association (BCCA). Dr. Gregory Skinner, a Clinical Advisor to the Company, gave a presentation that highlighted the use of the VMS+3.0 in retrieving volumetric and functional data for managing cardiac heart disease patients. The meeting took place on Monday 7th and Tuesday 8th of November 2022 at the International Conference Centre in Birmingham, UK. The BCCA meeting attracts over 400 delegates from across the UK and worldwide with a focus in adult and paediatric congenital cardiology. The attendees were members of various cardiac associations and health care professionals, which each year creates a valuable networking experience. Dr. Skinner's presentation will take place on November 8th, 2022 and is entitled: "Accurate, Reproducible Volumetric and Functional Data for Managing Congenital Heart Disease Using VMS From Ventripoint". The presentation focused on the unique abilities of the VMS+3.0 in the management of congenital cardiac patients through case studies and real-life examples. Exhibiting at the BCCA meeting continues Ventripoint's ongoing efforts to make the cardiology community aware of the benefits of the VMS+3.0 and allow them to have a hands-on experience of the ease of use of the system in the exhibition booth and then schedule an on-site demonstration at their clinic.

As part of the Company's ongoing efforts to promote awareness of its products and to increase its global footprint, Ventripoint participated in the 11<sup>th</sup> Cardiovascular Imaging Conference (DIC) hosted by the Brazilian Society of Cardiology (SBC), 29-31 July 2022, in Sao Paulo, Brazil. The SBC is Brazil's top professional association with 13,500 members in 26 regional societies throughout the country. The DIC-SBC conference, co-sponsored by major ultrasound suppliers in the industry, attracted participants from leading cardiovascular centers, research universities, private clinics and government. Ventripoint's podium presentation, "A Rapid, Accurate and Reliable Technique to Analyze RV Function in Echocardiograms from Patients with Congenital Heart Defects (CHD)", attracted 75 CHD clinicians. The presentation featured use of the company's novel AI-based tool (VMS+3.0) to analyze standard 2D echocardiograms to generate 3D model and cardiac measurements with accuracy equivalent to MRI for the Right Ventricle (RV) and other chambers of the heart. Dr. Gregory Skinner (Glenfield Hospital, UK) presented two case studies to showcase the benefits of using VMS+3.0 for long-term follow-up of pediatric patients with the CHD, Tetralogy of Fallot, following pulmonary valve replacement. Dr. Skinner also commented he routinely takes the VMS+3.0 to the patients within the hospital and has successfully analyzed the heart of a 2.3-kilogram, premature baby in the neonatal ICU. The presentation drew strong expressions of interest from leading clinicians and institutions looking to adopt the system. The need for VMS+3.0 units to diagnose CHD in South America is bigger than the United States. There are more children born with CHD in South America than North America (65,000 in North America and 71,000 in South America annually) and currently, there are 2.2 million adults with congenital heart disease in the United States, with more than 1.8 million in South America. (1) The Brazil healthcare market includes private companies, HMOs and public institutions. The system features dedicated cardiovascular centres and teaching hospitals that are world class such as Instituto do Coração (InCor USP), Hospital do Coração (HCor) and Instituto Dante Pazzanese de Cardiologia (IDPC) in Sao Paulo. The Company has engaged a representative in Brazil, and he has initiated discussions with KOLs, distributors and regulatory consultants to establish a market entry plan and assess

demand for VMS+ family of products in this rich region. The regulatory process in Brazil has recently been changed and it is estimated it will take 6 to 12 months to complete depending on the classification the VMS+. (1) John Jairo Araujo; "Adults with Congenital Heart Disease in the Americas - Where we are today and where we are heading: A General View of the Inter-American Adult Heart Disease Council ([https://www.sciencerepository.org/adults-with-congenital-heart-disease-in-the-americas-where-we\\_JICOA2020-3-102](https://www.sciencerepository.org/adults-with-congenital-heart-disease-in-the-americas-where-we_JICOA2020-3-102))

### **Chinese Partnership and Future Development**

In February 2021, the Company announced that its joint-venture partner Yutian Medical Shanghai Inc. ("Yutian") had informed the Company that it had achieved a number of milestones in its platform development to commercialization and is still ongoing.

### **VMS+3.0 Purchase Orders and Commitments to Customers**

Over the last year, Ventripoint has been in dialogue with major cardiovascular centres in K, and Europe. The Company has sold and delivered three VMS+3.0 machines to its Chinese partners for demonstration and research use and received full payment. In addition, Yutian has built and installed 8 QAS machines in China. The Company has also delivered one VMS+3.0 for 3D-echo – its software-only product, to a major European centre. This was the first sale of this product, which is able to analyze 3D echocardiograms from all major ultrasound machines.

### **Planned and Ongoing Clinical Studies**

The Company is currently assisting in planning or monitoring 15 investigator-initiated clinical studies where the VMS+3.0 is being used to improve diagnostics and improved patient care. Two of these studies are seeking to make the VMS+3.0 the "standard-of-care" in certain patient groups. In addition, the Company is in discussions to start 11 more externally-funded, investigator-initiated clinical studies proposed by leading cardiologists. There has never been a greater understanding for the need for better assessment of the heart and the unique ability of the VMS+3.0 to easily deliver quality data to allow physicians to confidently diagnose, treat and monitor their heart patients.

On March 1, 2022, the Company announced its support of a world-first study on maternal cardiovascular changes during pregnancy, which will be conducted at the Mazankowski Alberta Heart Institute in Edmonton, Alberta, Canada. This Heart & Stroke Foundation of Canada funded research will explore the contribution of inadequate heart function (use of Ventripoint) and vascular health and their interaction to adverse pregnancy outcomes. Use of the Ventripoint system will facilitate cardiac function investigations even in women with more challenging heart geometry. It is anticipated this innovative work will lead to improved strategies to optimize the cardiovascular health of these mothers leading to healthier pregnancies and infants."

Cardiovascular disease complicates 1-4% of pregnancies and is more common in women with hypertensive disorders, which is the leading cause of maternal death (Ramlakhan, K.P., Johnson, M.R. & Roos-Hesselink, J.W, 2020). One of the areas of focus for the study will be looking at the vascular and ventricular function in pregnant women with cardiovascular disease. A combination of vascular measuring techniques and heart assessments will be used to understand ventricular and vascular interactions in mothers during pregnancy. A study of this nature has never been attempted before and will provide fundamental information on changes in cardiac function during pregnancy. The VMS+3.0 will be used to perform heart assessments

in this study and will allow for quick, accurate and repeat measurements in this groundbreaking study of women's health.

The Company has thirteen investigator-initiated clinical projects underway or being planned. This shows the innovative nature of the VMS+3.0 in enabling clinicians to study a variety of heart problems by analyzing the whole heart for the first time. All these studies are being funded through institutional sponsorships or grants. The Company is providing equipment, training for research staff and logistical support for these ground-breaking studies which are conducted by leading cardiologists and the studies is still ongoing. The following five projects are currently underway:

1. Normal and Abnormal Maternal Heart Function during Pregnancy at the Mazankowski Alberta Heart Institute in Edmonton, Alberta, Canada under the direction of Dr. Lisa Hornberger, Principal Investigator and Dr. Jonathan Windram, Co-Investigator;
2. Congenital Heart Defects with Septal Defects; Canada, United States, UK, and Europe to expand sales of VMS+3.0 units. The Company received purchase orders and has committed to supply VMS+3.0 machines, but access to hospitals during COVID is limited. Some of these purchases will be on a lease and pay-per-use arrangement and so the Company will be building recurring revenue streams with these leading cardiac centres. The Company continues to build its sales funnel by actively marketing the VMS+3.0. Twenty five systems have been installed to date worldwide, with a projected additional 15 more installations before the calendar year end.

The COVID pandemic has the potential to dramatically increase the incidence and severity of heart disease. The US-CDC analyzed electronic health records for 63.4 million individuals estimated that 20% of COVID-19 survivors aged 18 to 64 years and 25% of survivors aged 65 years and older had a health condition related to their COVID infection. <sup>3</sup> In another large study<sup>4</sup>, it was concluded that regardless of severity of symptoms or vaccine status, COVID patients are 72 percent more likely to suffer from coronary artery disease and 63 percent more likely to have a heart attack. While most patients recover, their remains 5-10% who have "long-COVID", which is estimated could cost the US economy \$3.7 trillion. <sup>5</sup> As cardiologists work to clear the backlog of heart patients, that accumulated during the COVID pandemic, they are also reporting a higher proportion of their patients with more severe heart conditions. It remains to be seen if this was due to COVID accelerating their heart failure. Once again, since lung congestion is a major part of COVID, it is the right side of the heart that is most affected and the power of the VMS+3.0 to assess the right heart will be needed. <sup>6</sup> The Company is monitoring 2 clinical studies in COVID patients, who are being followed using the VMS+3.0 to determine the best ways to assess and treat these patients.

### **Expanding Product Distribution in Europe and North America**

The Company has a distributor partnership with a medical device distributor, CardioLogic Ltd. In the UK. CardioLogic Ltd specializes in the development, marketing, and distribution of medical devices for cardiac care and has an extensive network and customer base. Ventripoint does have prominent UK hospitals using the VMS+3.0, but the UK market is largely untapped. CardioLogic will expand Ventripoint's UK footprint with a sales team calling on echocardiologists, interventional cardiologists and cardiac surgeons, who would benefit from the VMS+3.0 system's fast and reliable diagnostic imaging. The process for purchase or lease of medical devices in the UK is controlled by Health Trusts and the National Health Service (NHS) and CardioLogic's experience in dealing with these processes will accelerate the approval of sales and allow a more rapid expansion into hospitals and cardiac facilities across the UK.

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The Company has appointed Angiopros GmbH as Ventripoint's European Distributor for Ventripoint's products and has engaged AngioConsult, their affiliated company, to tailor the marketing efforts to the different countries in the EU. AngioConsult and Angiopros are both based in Germany. While AngioConsult is a consulting firm that specializes in market access, product management, sales organization as well as training programs in one company, Angiopros is a classic distributor company focusing on the distribution of medical devices and software products in the cardiology, vascular surgery, and radiology/angiology fields. AngioConsult will combine its consulting arm with its distribution partner, Angiopros, to position Ventripoint in the European market. AngioConsult was selected based on its reputation in the cardiovascular market, alignment with Ventripoint's current customer base, and an extensive distribution network with contacts to professional decision makers in the cardiovascular field.

The Company continues to interview additional potential European and North American distribution partners.

In November 2022, The Company appointed MediTek Lifesciences LLC as Distributor for the USA-California market. MediTek distributes products specific to cardiology research and treatment centers throughout the State of California, USA. California's economy is poised to be the 4th largest in the world (<https://www.bloomberg.com/opinion/articles/2022-10-24/california-poised-to-overtakegermany-as-world-s-no-4-economy>), California has a number of leading cardiac centers and is an excellent base to begin to advance cardiac diagnostics in the USA. MediTek has multiple sales representatives with a combined experience of over 45 years in the cardiology sector within the Californian market and understand how the VMS+ meets doctors' needs by providing reliable echocardiography measurements. The representatives have completed training and their initial focus will be the clinicians and cardiologists who treat patients with congenital heart disease, which is a life-long condition where accurate regular assessments of right-heart function are critical to the planning and monitoring of appropriate care. With an established customer base of more than 100 clinical sites, MediTek will grow Ventripoint's awareness within the California market and further expand its customer base.

The Company has also increased its sales team in May 2022 with the hires of two strategic sales account managers for U.S., Europe, and UK. These sales personnel will assist in the expansion of global sales. Each account manager has the required skill set for managing the sales and distribution of the VMS+ product on a global scale. The account manager in charge of the United Kingdom/European sales and distribution has over two decades of experience in medical device sales. He has managed international sales teams within the cardiac device market, as well as worked extensively with multiple distributors. Ventripoint will benefit from the entrepreneurial and start-up mindset of this new hire and is expecting to see an increase in sales with this added support. The account manager in charge of the United States sales and distribution also has over two decades of experience in medical device sales. He has experience working with contracting Group Purchasing Organizations (GPOs) and Integrated Delivery Networks (IDNs). They also have extensive experience training multiple teams of clinical sales representatives, along with managing teams of clinical sale specialists. Ventripoint has been rapidly growing within the past year and has been expanding into new markets. The two sales account managers will be an integral part of Ventripoint's sales and marketing efforts towards meeting and surpassing the sales goals of the VMS+.

#### **New CPT Code**

At the recommendation of the AMA (American Medical Association), the U.S. Department of Health and Human Services (HHS) through CMS (Centers for Medicare & Medicaid Services) has finalized a CPT

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(Current Procedural Terminology) billing code (+93319) for 3D echocardiographic imaging and postprocessing during transesophageal or transthoracic echocardiography. Effective January 1, 2022, the CPT billing code will be a new compensation for doctors to analyze 3D echocardiograms and can be used by doctors and hospitals to claim reimbursement from payers (Medicare, Medicaid, insurance companies, etc.). This is a significant development for 3D echocardiography, which has struggled to be adopted due to poor image quality and difficulty of analysis. Our 3D echo VMS+ product has recently been shown (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8250005/>) to yield excellent results in 75% of children for the most difficult heart chamber, the right ventricle. The Company believes it can accelerate the adoption of 3D echocardiography by improving the ease and success rate of reading the exams and generating MRI-grade measurements for all 4 chambers of the heart. There will always be a need for VMS+3.0 to analyze 2D echocardiography exams for the 25% of patients who generate unreadable images in 3D scans. The VMS+ systems (2D and 3D) are fast and reliable ways to assist in diagnosing and monitoring patients with heart defects and other cardiac issues. Now the VMS+ 3D can also help in driving the adoption of an additional source of billable income for doctors.

### **Clinical Advisory Board**

The Company is assembling a clinical advisory board with the appointments of Dr. Gregory Skinner in February 2022 (see NR February 2, 2022) and Dr. Howard Michael Leong-Poi in April 2022 (see NR April 19, 2022). Dr. Jose Banchs joined the clinical advisor board in April 2022 (see NR April 27, 2022).

Dr. Skinner is currently a Consultant Paediatric Cardiologist at the East Midlands Congenital Heart Centre in Leicester, UK and is the Clinical Lead for the Department of Paediatric Cardiology and Deputy Head of Service for the East Midlands Congenital Heart Centre. On top of paediatric cardiology, Dr. Skinner is well versed in advanced imaging, particularly transthoracic and transesophageal echocardiography in congenital heart disease. He also specializes in paediatric and congenital cardiac x-ray computed tomography (CT) and magnetic resonance imaging (MRI). Dr. Skinner is certified in Congenital Heart Disease Echocardiography from the European Society of Cardiovascular imaging and a member of the Royal College of Paediatrics and Child Health (MRCPCH).

Dr. Howard Leong-Poi is Head of the Division of Cardiology, as well as the Medical Director of the Heart and Vascular Program at St. Michael's Hospital in Toronto, Ontario. He is also a Full Professor of Medicine at the University of Toronto. He is currently an Associate Editor for the Canadian Journal of Cardiology and has published over 100 articles in peer-reviewed journals. Dr. Leong-Poi has served on multiple grant review panels, such as the CancerCare Manitoba Foundation, Swiss National Science Foundation, Canadian Foundation for Innovation, and others. He is a member of the Institute of Medical Sciences, Canadian Society of Echocardiography, Canadian Cardiovascular Society, and other notable associations. Dr. Leong-Poi has received numerous international awards, including the 2017 Feigenbaum Lecturer, recipient of the 2005 William W. Parmley Young Author Achievement Award, and 1st prize for the Research Award Competition for the American Society of Echocardiography. Dr. Leong-Poi's clinical research interests focus on cardiac imaging, specifically echocardiography, in coronary artery disease, heart failure and valvular heart disease. His extensive experience and clinical research will bring insight and ideas for the development of the VMS+ system to better diagnose and monitor cardiovascular disease.

Dr. Banchs has been involved with Ventripoint's development for the past few years and will now take on a leadership role for clinical development. Dr. Banchs is the current Director of Echocardiography at the University of Colorado's Anschutz Medical Campus as well as a Professor of Medicine in the Cardiology

Division at the University of Colorado. He is a diplomate of the American Board of Internal Medicine in Cardiovascular Disease and the National Board of Echocardiography.

Dr. Banchs has been a consultant for numerous organizations across the United States over the years. His extensive experience and excellence in both research and teaching has earned him many honors and awards. He has been recognized as TX Top Doctor 2020 and 2019, received the Faculty Teacher of the Year Award for multiple years in a row and in 2021 was the recipient of the ASE Meritorious Service Award.

Dr. Banchs has an extensive list of published work within the biomedical field, such as research articles, book chapters, and abstracts. Based on 2018 data, there are 2,380 deaths from cardiovascular disease each day in the US. Ventripoint aims to bring a faster and reliable diagnostic tool for cardiac disease with the help of experts like Dr. Banchs. Dr. Banchs will bring the insight he has gained as a top doctor in the cardiology field as well as the latest research in cardiology developments to Ventripoint.

### **Marketing Outreach and OTCQB Up-listing**

The Company up-listed to the OTCQB tier effective on January 7, 2022 (see NR January 7, 2022). Online investors now have easy access to trading through their own local accounts. In addition, this status should broaden exposure on many different online platforms. The Company trades on the OTCQB exchange under symbol "VPTDF"; the Company's common shares will continue to trade on the Toronto Securities Venture Exchange under the symbol "VPT". The Company has also engaged specialty groups in Europe and abroad to assist in this process. As our sales and distribution expands, so will our outreach. With many important announcements expected this fall and winter, our objective is to reach an expanding global audience of investors.

### **DTC Eligibility Approval**

On March 21, 2022, the Company announced that Ventripoint's common shares are now eligible for electronic clearing and settlement through the Depository Trust Company ("DTC") in the United States ("US"). DTC is a subsidiary of the Depository Trust & Clearing Corp., which manages the electronic clearing and settlement of publicly traded companies in the US. DTC eligibility incorporates an electronic method of clearing securities that accelerates the receipt of stock and cash, reduces costs, and allows the stock to be traded over a much wider selection of brokerage firms by meeting their clearing and settlement requirements.

### **Commercialization**

The Company has sold or has new orders and commitments for the VMS+3.0 devices. New orders have not been fulfilled due to the temporary restrictions of hospitals as they deal with the COVID-19 pandemic. To date, the Company has installed machines in cardiac centres in North America, U

3. LA Enlargement as an Earlier Indicator of Heart Failure with Diastolic Dysfunction;
4. Right Atrial (RA) and Right Ventricular (RV) Enlargement as an Indicator of Tricuspid Valvular Dysfunction;
5. Retrospective Analysis of Benefits of VMS+3.0 for Determining Optimal Point for Pulmonary Valve Replacement (PVR) in Young Adults with Tetralogy of Fallot;
6. Single ventricle cardiac function in children with Dr. Piers Barker as the lead investigator at Duke Pediatric and Congenital Heart Center.

The other seven studies will address, hypertension, cardiotoxicity, valvular disease, Duchenne muscular dystrophy, acute COVID-19, long-haul COVID-19, COVID-19 in elite athletes and surgical planning in valve replacements.

The Company will provide details on these studies when they have been approved by the host institutions.

In June 2022, the Company reported that one of the aforementioned clinical projects was underway which included a collaboration with Duke University School of Medicine in a new study that analyzes single ventricle cardiac function in children. This will be the first study to validate the VMS+3.0 in children with functional single ventricles. “The goal of non-invasive pediatric cardiac imaging is always to make the most accurate diagnosis, while simultaneously disturbing the child as little as possible” states Dr. Piers Barker, Pediatric Cardiologist at the Duke Pediatric and Congenital Heart Center. “New 3-dimensional technologies could have the potential to help us better achieve that goal for our patients with the most complex congenital heart disease.” Congenital heart disease represents the most common single organ birth defect, with an incidence of approximately 1 in 100 live births. Many of these children are born with critical congenital heart disease, requiring cardiac surgery or other interventions before their first birthday to survive. One of the most critical conditions occurs when children have only a functional single ventricle, in which only one of the two pumping chambers is developed. These children require the most intensive diagnostic and interventional care due to the enormous complexity of how each heart forms, through infancy and into adulthood. Children with functional single ventricles typically undergo a series of three staged surgeries in order to achieve adequate blood flow to both the body and the lungs. However, complications and a risk of heart failure accompany every stage, with the risk becoming greater as children approach adulthood. Standard echocardiography assessments are difficult to apply to these patients given how different the cardiac anatomy is as compared to a normal heart. Novel, 3-dimensional diagnostic tools like VMS+3.0 therefore provide a great opportunity to accurately assess heart function and enable proactive treatment prior to the development of heart failure or deterioration to the point of transplantation or death. The research study will utilize the strengths of the Ventripoint system with the patient databases of the Duke Pediatric and Congenital Heart Center and the Duke Cardiovascular Magnetic Resonance Center to validate the VMS+ for use in this patient population.

### **Business Objectives and Milestones**

The Company has the following milestones:

- Grow cumulative cardiac base in United States, Europe, and United Kingdom (See “VMS+3.0 Purchase Orders and Commitments to Customers” and “Commercialization” above). The Company is building a small direct salesforce and partnering with distributors to accelerate sales of its products. It will need to hire additional staff for sales, management of distributor and preparation of marketing material. The Company intends to exhibit at a number of major cardiology and medical device conferences in the next year to build brand awareness and build its sales funnel.
- GE Healthcare product resulting from collaboration (see “Distribution Agreements” and “GE Healthcare Collaboration” above). The Company will continue to collaborate with GE Healthcare to result in a fully validated product, which is developed by the Company in-house and validated by GE Healthcare. The Company will require additional staff to participate in the planning of the launch of the product by GE Healthcare and to prepare supporting documentation for regulatory

submissions and marketing, as well as training and support for GE Healthcare's salesforce. The Company will also need additional application specialists to train and support GE Healthcare's application specialists during sales and for aftersales support of customers. The Company is also looking for clinical sites to further validate the product in existing and new applications. Estimated costs through to Q3 2022 is \$570,000 for operations and commercialization and \$322,000 for product design and development.

- Upgrade of VMS+3.0 to VMS+4.0. The next generation of the Company's products will be focused on 4D (motion) analysis and enhanced tracking and user-friendly features to accelerate analysis and optimize visualization of all 4 chambers of the heart. The new design will also significantly lower the cost of manufacturing the product. This design and development will be done by Ventripoint in-house. It is estimated that the completion of the development of the VMS+4.0 and validation, regulatory market approvals and transfer to production will occur within the next 12 months. Regulatory market approvals will be done by the Company in-house. Current facility is scaled to manufacture at least 3 units/week with a full-time assembler and quality control personnel. Estimated costs through to Q4 2022 is \$1,710,000 for Operations and commercialization and \$966,000 for product design and development.

### **Current Focus for Clinical Applications**

#### **1. Congenital Heart Disease**

Children born with a heart abnormality almost universally have the defect in the right ventricle (RV). The VMS+ system was originally developed to address this need and it continues to be a focus for the Company. Currently, a number of pediatric hospitals are using the VMS+2.0 or VMS+3.0 to evaluate such patients as it is critical to monitor the size of the RV as the children grow to be sure it is not dilated. There is significant risk of permanent damage to the RV, if it is left dilated for an extended period. Hence the ASE guidelines call for an echocardiogram with estimation for RV size every 3 months. Stollery Children's Hospital, The Alberta Children's Hospital, The Hospital for Sick Children and Sofia Hospital in Rotterdam have VMS+3.0 systems.

While tetralogy or fallot and septal shunts are the majority of CHD patients (about 1% of all births), there are a number of other more rare but clinically challenging abnormalities. The Company continues to assist with studies on these types of CHD patients a major children's hospitals around the world.

CHD patients now live a normal life span and so there are a number of adult CHD patients who still need to be monitored for RV dilation throughout their life. Toronto General Hospital (see NR November 5, 2020) has a large cohort of these patients and this one of the foci for the use of the VMS+3.0.

#### **2. Pulmonary Hypertension (PH) and COVID**

Lung congestion results in increased blood pressure in the pulmonary artery. This results in increased load on the right heart and dilation of the RV. There are now a number of drugs to treat PH and it is critical to determine when a particular drug is effective and when to change to another therapy. Once again, if the RV is allowed to be dilated for a long time, there is a great chance of



right heart failure and death. The ASE guidelines call for echocardiogram and RV size determinations every 3 months, but this is not done currently as the standard technique to quantify RV size is not reliable. The VMS+3.0 has been verified to give accurate and reliable results equivalent to MRI in PH patients. One of the foci for the Hospital for Sick Children and the Toronto General Hospital (see NR November 5, 2020) is to use the VMS+3.0 on pediatric and adult PH, respectively.

Lung congestion and RV dilation is being seen now in COVID patients worldwide and there have been studies correlating RV size with mortality in ICUs. It is now clear COVID-19 significantly damages the heart and results in both acute and chronic cardiac dysfunction. The Company is engaging with two major cardiac centres to conduct clinical studies on COVID-19 patients. The literature has shown RV, LV and biventricular dysfunction can be detected with echocardiography using crude analysis of the heart. The Company anticipates it will be able to significantly improve the results for echocardiograms from COVID-19 patients. King's College London is primarily focused on using the VMS+3.0 in COVID patients.

3. Cardiotoxicity of Chemotherapy Treatments for Cancer.

There is a growing literature base to show all chemotherapy agents are cardiotoxic, with many patients developing chronic heart disease following cancer therapy. A study published in Echo Res Pract. (2016, Sept 3(3): 79-84) entitled "Right heart function deteriorates in breast cancer patients undergoing anthracycline-based chemotherapy", by a group led by Dr. Boczar at the University of Ottawa Heart Institute, Ottawa, Ontario, Canada, concluded: "This study demonstrates that breast cancer patients receiving anthracycline-based chemotherapy experience adverse effects on both right atrial size and RV function". The Ottawa Heart Institute has purchased a VMS+3.0 system. The Company has been contacting cardiologists within cancer centers to determine the need to accurately determine RA and RV size and function during and after cancer therapy.

There are 1.7M new cancer patients/year in the USA. The lifetime risk of cancer is 42% in men and 38% in women. Cancer has surpassed cardiovascular disease as the number one killer in the USA with 600,000 deaths per year. The leading cause of death in cancer, for both women and men (27%), is lung cancer where RV failure is a major risk. Direct medical costs for cancer in the US in 2013 were \$74.8B billion and \$30B (40%) were for inpatient hospital stays. In the USA, there are more than 1,400 cancer-care facilities, which are accredited by the Commission on Cancer of the American College of Surgeons. These centers have been adding cardiologist to their staff as cardiotoxicity is now well established.

MD Anderson Hospital received a VMS+3.0 system (see NR October 8, 2020) to use for routine clinical assessment of oncology patients to determine cardiac changes during and after treatments.. When the Company met with the cardiology team to assess their experience to date, they indicated the VMS+3.0 resolved all their operational concerns. MD Anderson has been one of the top two cancer centers in the USA for decades. It receives the highest number of research grants from the National Cancer Institute and is the recognized leader in the diagnosis and treatment of cancer.

A key addition to the VMS+3.0 was a complete workstation to allow remote analysis of echocardiograms in viewing rooms within the hospital. Unlike Europe where the cardiologist captures and analyzes the images on the ultrasound unit, in the United States, sonographers collect

the images into a standardized DICOM file and upload them to an internal server (PACS) so they can be retrieved and analyzed by a cardiologist in a viewing room. Viewing rooms are equipped with workstations and high-resolution screens to optimize the images. Accordingly, the Company elected to incorporate a workstation into the VMS+3.0. While the VMS+3.0 is designed to deal with low-quality images and allow for analysis on the unit itself, it never hurts to have optimal viewing conditions.

#### 4. Technically-Difficult Imaging

Technically-difficult imaging is a continual problem in echocardiography. About 20-30% of patients yield unreadable images using conventional 2D echo due to their particular anatomy. When a result is needed, a contrast medium is injected into the patient while the study is re-done to increase the contrast between the heart muscle and the blood. This results in a readable image about 80% of the time, but the procedure has a number of drawbacks. It takes extra time as the study needs to be redone. It requires a patient to approve an infusion and requires an IV nurse to be summoned to do the infusion, which can also take time. As well, the contrast media is expensive and only provides one view (typically apical 4-chamber view) as compared with the 16 views taken during a standard echocardiogram. With conventional 2D echo, there are usually some views that can be difficult to interpret due to either borders that are not easily distinguishable or areas of drop out (fading). The VMS only needs a small number of points to analyze the heart and once the heart can be located in the views, other anatomical landmarks become recognizable. The Company believes it can significantly reduce the use of contrast media, which would save time, money and patient discomfort.

The Company installed the VMS+3.0 whole heart analysis system at the University of Alberta Mazankowski Alberta Heart Institute under the supervision of Dr. Jonathan Windram, Staff Cardiologist, Northern Alberta Adult Congenital Heart Program and Associate Clinical Professor of Medicine, Division of Cardiology, Department of Medicine, University of Alberta Mazankowski Alberta Heart Institute. The first clinical study addressed technically-difficult patients and the ability of the VMS+ to reduce the use of contrast media. In 10-25% of patients the images collected by standard 2D ultrasound are not clear enough to allow for interpretation using conventional methods. Using the artificial intelligence (AI) approach embedded in the VMS+ heart analysis system, the standard images can be analyzed. Normally in these patients, a second exam is immediately performed using the injection of a contrast media, which enhances the ability to see the heart walls and allows for conventional analysis in most cases. The reduction in the number of contrast-enhanced 2D echo studies would represent a significant savings in time and costs for echocardiology departments. It would also reduce the need to inject the patient with contrast media. The use of contrast-enhanced ultrasound is increasing in the western world with the burgeoning population of heavier people making it more difficult to obtain clear images using ultrasound.

The Mazankowski Alberta Heart Institute is the advanced cardiac care center for Edmonton, Northern and North-Central Alberta, Northern BC, Saskatchewan, Manitoba, Yukon and Northwest Territories. Located on the Walter C. Mackenzie Health Sciences Centre Campus in Edmonton, Mazankowski is physically integrated with the University of Alberta and Stollery Children's Hospitals, making it one of the very few heart institutes to accommodate both adult and pediatric patients. The Mazankowski has one of the most technologically advanced echo labs in the world employing leading-edge imaging techniques.

The Company will be focusing on the above four applications and approaching leading cardiologists who have published in these areas to make them aware of the VMS+3.0.

### **Off-Balance-Sheet Arrangements**

As of the date of this filing, the Company does not have any off-balance-sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Company, including, and without limitation, such considerations as liquidity and capital resources.

### **Proposed Transactions**

The Company routinely evaluates various business development opportunities which could entail optioning properties, direct acquisitions, trades and/or divestitures. In this regard, the Company is currently in discussions with various parties, but no definitive agreements with respect to any proposed transactions have been entered into as of the date of this MD&A. There can be no assurances that any such transactions will be concluded in the future.

### **Discussion of Operations**

#### **Three months ended September 30, 2022, compared with three months ended September 30, 2021**

The Company's recorded sales of \$15,460 and a net loss totaled \$1,404,688 for the three months ended September 30, 2022, with basic and diluted loss per share of \$0.01. This compares with a net loss of \$730,836 with basic and diluted loss per share of \$0.01 for the three months ended September 30, 2021. The decrease in net loss was principally because:

- For the three months ended September 30, 2022, general and administrative expenses was \$974,754, compared to \$579,120 for the three months ended September 30, 2021. The increase in general and administrative was primarily due an increase in investor relations and offset by lower share-based compensation.
- For the three months ended September 30, 2022, research and development expenses was \$194,216, compared to \$106,874 for the three months ended September 30, 2021. The increase in research and development was primarily due salaries and external consultants with specialized knowledge in product testing and regulatory.
- For the three months ended September 30, 2022, sales and marketing expenses was \$276,714, compared to \$58,824 for the three months ended September 30, 2021. The increase in sales and marketing was due higher media setup and management.

#### **Nine months ended September 30, 2022, compared with nine months ended September 30, 2021**

The Company's recorded sales of \$40,060 and a net loss totaled \$3,768,472 for the nine months ended September 30, 2022, with basic and diluted loss per share of \$0.02. This compares with a net loss of

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\$2,784,454 with basic and diluted loss per share of \$0.02 for the nine months ended September 30, 2021. The decrease in net loss was principally because:

- For the nine months ended September 30, 2022, general and administrative expenses was \$2,570,048, compared to \$2,031,322 for the nine months ended September 30, 2021. The increase in general and administrative was primarily due an increase in investor relations and offset by lower share-based compensation.
- For the nine months ended September 30, 2022, research and development expenses was \$687,247, compared to \$304,913 for the nine months ended September 30, 2021. The increase in research and development was primarily due salaries and external consultants with specialized knowledge in product testing and regulatory.
- For the nine months ended September 30, 2022, sales and marketing expenses was \$576,107, compared to \$189,344 for the nine months ended September 30, 2021. The increase in sales and marketing was due higher media setup and management.
- For the nine months ended September 30, 2022, warrant liabilities revaluation was \$nil, compared to (\$229,087) for the nine months ended September 30, 2021 as warrants were exercised during the nine months ended September 30, 2021.

### **Liquidity and Financial Position**

The activities of the Company, principally the development and commercialization of diagnostic tools to monitor patients with heart disease, are financed through the completion of equity transactions such as equity offerings and the exercise of stock options and debt financing. There is no assurance that debt financing and equity capital will be available to the Company in the amounts or at the times desired or on terms that are acceptable to the Company, if at all.

Cash used in operating activities was \$3,768,472 for the nine months ended September 30, 2022, compared to \$2,002,316 for the nine months ended September 30, 2021. Operating activities for the nine months ended September 30, 2022, were affected by net loss of \$3,768,472 plus adjustments of \$791,468 primarily related to share-based compensation and consulting fees settled with shares, and the negative change in non-cash working capital balances of (\$114,708), primarily related to increase in amounts receivable and decrease in accounts payable and other liabilities.

Cash provided used in financing activities was \$74,924 for the nine months ended September 30, 2022, compared to cash provided by financing activities of \$4,528,013 in the nine months ended September 30, 2021. Financing activities for the nine months ended September 30, 2022, primarily included \$98,450 for the exercise of options Financing activities for the nine months ended September 30, 2021, primarily included \$3,936,116 for the exercise of warrants.

Cash used in investing activities was \$nil for the nine months ended September 30, 2022, compared to \$4,257 in the nine months ended September 30, 2021, as a result of additions to equipment.

At September 30, 2022, the Company had \$6,209,862 in cash and cash equivalents (December 31, 2021 - \$9,268,963).

The Company has minimal revenues and therefore must utilize its funds obtained from the equity financing and other financing transactions to maintain its capacity to meet ongoing the commercialization of VMS+3.0.

As of September 30, 2022, and to the date of this MD&A, the cash resources of the Company are held with the Canadian Imperial Bank of Commerce and Royal Bank of Canada.

The Company's use of cash at present occurs, and in the future will occur, principally in two areas, namely, funding of its general and administrative expenditures and funding of its development and commercialization activities. The Company has no development commitments on its property interests over the next 12 months. Management may reassess its planned expenditures based on the Company's working capital resources, the scope work required to advance exploration on its projects and the overall condition of the financial markets.

The Company's working capital of \$5,507,068 at September 30, 2022, (December 31, 2021 - \$8,416,869), and is sufficient to satisfy current liabilities and general and administrative costs for it to continue operations for the twelve-month period ending September 30, 2023

## **Recent Accounting Pronouncements**

### **New Accounting Standards Adopted**

Certain pronouncements were issued by the IASB or the IFRIC that are mandatory for accounting periods commencing on or after January 1, 2022. None are applicable or do not have a significant impact to the Company and have been excluded.

### **New Standards Not Yet Adopted And Interpretations Issued But Not Yet Effective**

Certain pronouncements were issued by the IASB or the IFRIC that are mandatory for accounting periods commencing on or after January 01, 2023. Management is still assessing the impact, if any, the new accounting pronouncements will have on the financial statements.

## **Critical Accounting Estimates**

The preparation of the consolidated financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenue and expenses.

Information about critical judgments in applying accounting policies and assumptions and estimation uncertainties that have the most significant effect on the amounts recognized in the consolidated financial statements includes the assumptions and model used to estimate share-based compensation and the valuation of warrants and other derivative liabilities, the capitalization and expensing of development costs, the impairment of assets which requires judgement in determining if the facts and circumstances suggest that the carrying amount exceeds the recoverable amount, the allocation of revenues between amounts recognized upon installation and amounts deferred and recognized over the initial warranty period, the designation of the Canadian dollar as the Company's functional currency, and factors considered in inventory obsolescence.

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Reported amounts and note disclosure reflect the anticipated measures management intends to take. Actual results could differ from those estimates. The above estimates and assumptions are reviewed regularly. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

### **Related Party Transactions**

Related parties include the Board of Directors, close family members and enterprises that are controlled by these individuals as well as certain persons performing similar functions. Related party transactions conducted in the normal course of operations are measured at the amount established and agreed to by the related parties.

(a) Remuneration of directors and key management personnel of the Company was as follows:

	Three months Ended		Nine months Ended	
	September 30, 2022 \$	September 30, 2021 \$	September 30, 2022 \$	September 30, 2021 \$
Salaries, fees and short-term benefits	111,937	60,000	201,937	120,000
Share-based payments	75,340	19,716	136,997	49,484
Directors fees	21,000	Nil	63,000	Nil
<b>Total</b>	<b>170,955</b>	<b>79,716</b>	<b>551,889</b>	<b>248,629</b>

Executive Officers and Directors participate in the Stock Option Plan and the DSU Plan. Officers also participate in the Company's health plan. Directors receive monthly and meeting fees for their service.

(b) Other transactions of directors and key management personnel of the Company was as follows:

- For the three and nine months ended September 30, 2022, the Company expensed \$20,329 and \$56,438, respectively (three and nine months ended September 30, 2021 - \$18,504 and \$65,076, respectively) to Marrelli Support Services Inc. ("Marrelli") for: the Chief Financial Officer ("CFO") of the Company; and for bookkeeping services. The CFO is an employee of Marrelli. These services were incurred in the normal course of operations for general accounting and financial reporting matters.
- On January 13, 2021, directors of the Company converted \$250,000 of the February 6, 2020, convertible debt into 3,333,332 shares.
- On February 16, 2021, a director of the Company exercised 100,000 options at an exercise price of \$0.10, with an expiry date of January 12, 2031.
- On February 19, 2021, an officer and director of the Company exercised 466,799 warrants at an exercise price of \$0.10, with an expiry date of February 6, 2022.

- On February 23, 2021, the Company issued to an officer and directors of the Company, 30,186 shares for debt for final interest on convertible debt.
- As at September 30, 2022, \$67,366 (December 31, 2021 - \$98,873) was included in accounts payable and accrued liabilities due to related parties.

### **Disclosure of Internal Controls**

Management has established processes to provide them sufficient knowledge to support representations that they have exercised reasonable diligence that (i) the unaudited condensed interim consolidated financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the unaudited condensed interim consolidated financial statements; and (ii) the unaudited condensed interim consolidated financial statements fairly present in all material respects the financial condition, results of operations and cash flows of the Company, as of the date of and for the periods presented.

In contrast to the certificate required for non-venture issuers under National Instrument 52-109 Certification of Disclosure in Issuers' Annual and Interim Filings ("NI 52-109"), this Venture Issuer Basic Certificate does not include representations relating to the establishment and maintenance of disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"), as defined in NI 52-109. In particular, the certifying officers filing this certificate are not making any representations relating to the establishment and maintenance of:

- i) controls and other procedures designed to provide reasonable assurance that information required to be disclosed by the issuer in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and
- ii) a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the issuer's GAAP (IFRS).

The issuer's certifying officers are responsible for ensuring that processes are in place to provide them with sufficient knowledge to support the representations they are making in this certificate. Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost-effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

### **Risks and Uncertainties**

An investment in the securities of the Company is highly speculative and involves numerous and significant risks. Such investment should be undertaken only by investors whose financial resources are sufficient to enable them to assume these risks and who have no need for immediate liquidity in their investment. Prospective investors should carefully consider the risk factors that have affected, and which in the future

are reasonably expected to affect, the Company and its financial position. Please refer to the section entitled "Risk and Uncertainties" in the Company's Annual MD&A for the fiscal year ended December 31, 2021, available on SEDAR at [www.sedar.com](http://www.sedar.com).

### **Additional Funding Requirements**

The Company's success in raising new operating capital has enabled it to finalize its VMS+ development and implement initial commercialization strategies. The Company will require additional operating capital to sustain and grow the level of its operations and to further implement its commercialization strategies. The Company is in discussions with multiple parties related to its financing, development and commercialization efforts to secure sufficient additional capital and resources for commercialization of its VMS+ technology and to achieve cash flow break-even. The need, success and timing of additional financings and/or strategic relationships cannot be projected with any certainty and their ultimate success is necessary for the Company to continue operations and to achieve its near term commercial and development milestones.

### **Continued Operations**

Without sufficient additional capital being secured in a timely manner, Company operations may have to be curtailed; the result of which could render the Company unable to pursue commercialization of its products and services, or to continue its operations.

There is no certainty whether the Company will generate significant revenues or attain profitable operations in the near future and there can be no assurance that it will achieve profitability in the future, as it incurred a loss of \$3,768,472 and had a negative cash flow from operating activities of \$3,091,712 for the nine months ended September 30, 2022, and has accumulated \$47,516,684 of losses as at September 30, 2022 (December 31, 2021 - accumulated losses of \$43,748,212). As a result, there is a material uncertainty which creates significant doubt regarding the Company's ability to continue as a going concern. The Company's ability to continue as a going concern is dependent on its raising of future required capital, bringing its products to market and achieving and maintaining profitable operations. The outcome of these matters cannot be predicted at this time

### **COVID-19**

Since December 31, 2019, the outbreak of the novel strain of coronavirus, specifically identified as "COVID-19", has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The duration and impact of the COVID-19 outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operations in future periods.



### **Subsequent events**

- Subsequent to September 30, 2022, 120,000 stock options with an exercise price of \$0.25, and expiry date of February 5, 2023, were exercised.
- Subsequent to September 30, 2022, 110,000 warrants with an exercise price of \$0.115 and expiry date of October 2, 2022, were exercised: