



## **VENTRIPOINT DIAGNOSTICS LTD.**

### **MANAGEMENT'S DISCUSSION AND ANALYSIS FORM 51-102F1**

**For the nine months ended September 30, 2018**

**November 29, 2018**

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## **MANAGEMENT’S DISCUSSION AND ANALYSIS, AUGUST 29, 2018**

This management’s discussion and analysis of operations and financial position (MD&A) should be read in conjunction with Ventripoint Diagnostics Ltd.’s (‘Ventripoint’ or the ‘Company’) unaudited condensed consolidated interim financial statements and the corresponding notes thereto for the nine months ended September 30, 2018. Ventripoint’s condensed consolidated interim financial statements have been prepared in accordance with International Accounting Standard 34 - *Interim Financial Reporting*.

Unless otherwise specified, all financial data is presented in Canadian dollars. This MD&A is as of November 29, 2018.

### **CAUTIONARY STATEMENT 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.

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;

- Product and service related approvals will be obtained from all necessary agencies in a timely manner and without unplanned additional costs; and
- The Company will have sufficient resources to implement its strategies in a timely and effective manner.

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.

## Stock Market Award and Activity



On February 22, 2018, the Company was named to the 2018 TSX Venture 50, a ranking of the top performers on the TSX Venture Exchange during 2017. It was a historical year for Ventripoint, our employees and shareholders, who saw the Company increase its market capitalization by 384% and share price appreciation of 258%, while trading 206 million shares on the TSX Venture Exchange and 250 million shares on all exchanges.

This despite having only 50 million shares issued. This trend continued in 2018 with 100 million shares traded on all exchanges year to date. As of October 23, 2018, the Company's common shares trade on the OTCQB Venture Market under the stock symbol 'VPTDF'. Investors can find Real-Time quotes for the Company on [www.otcmarkets.com](http://www.otcmarkets.com). As a verified market with efficient access to U.S. investors, OTCQB will help Ventripoint to build shareholder value with a goal of enhancing liquidity and achieving fair valuation. It will allow the Company to engage a far greater network of U.S. investors, data distributors and media partners, ensuring U.S. investors have access to the same high-quality information that is available to investors in Canada.

## OVERVIEW

Ventripoint is a medical device company engaged in the development and commercialization of its diagnostic tools to monitor patients with heart disease – a major cause of death in developed countries and a rapidly rising incidence in emerging countries. 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 with critical volume and functional measurements of a patient's heart chambers 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+ system (hardware and software for 2D echocardiograms) and VMS+ software (software only for 3D echocardiograms) have US FDA marketing clearance, Health Canada license and European CE Mark for all patients, where volumetric information for any of the four chambers of the heart is warranted or desired.

The Company is in the early stages of commercialization. As further described below, current efforts are focused on:

- Marketing the 4-chamber VMS+ for 2D and 3D in Canada, Europe, the USA.
- Obtaining regulatory approvals for the 4-chamber VMS+ in other jurisdictions including China;
- Continued clinical evaluation of the 4-Chamber VMS+ to determine its optimal use in medical settings;
- Establishing partnerships to develop an integrated 2D ultrasound machine and expand the software analysis tools using advanced artificial intelligence (AI) approaches;
- Supporting our partnership to manufacture, market and distribute existing and future VMS products in China. The Company has retained the rights to market existing and any new devices outside of China;
- Completing a VMS-4DE application in partnership with the National research Council; and
- Further advancing and developing the technology and product to extend and expand its acceptance and usability.

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 reduce the cost of healthcare for these patients by billions of dollars 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.

## **HIGHLIGHTS AND CURRENT DEVELOPMENTS**

The Company has made significant progress in implementing its development and commercialization plans. Approvals have been obtained in Canada, Europe and the USA to market the VMS for all types of heart disease where the volumetric information for any of the four chambers of the heart is warranted or desired. The Company announced the granting of a license for the VMS+ (hardware and software for 2D) from Health Canada for all four chambers of the heart on March 2, 2017, received CE Mark on December 15, 2017 and market clearance from the US-FDA on May 18, 2018. The VMS product remains the only approved way to generate substantially equivalent results to the gold-standard MRI for heart chamber volumes using 2D echocardiography.

On October 17, 2018, the Company announced that Jessica Naman had joined Ventripoint as Marketing Manager and will be responsible for conceiving and executing marketing strategies and tactics for the growth of the current VMS+ system along with the rollout and expansion of the next generation product line. Jessica is implementing a comprehensive corporate branding strategy to enhance Ventripoint's recognition as a global leader in whole-heart analysis through the development of public relations,

interactive online media and creative strategies. She will be leading the team in the pre-launch plan as we showcase the next generation system at EuroEcho 2018 in Milan, Italy this December, and will explore further opportunities in the future of 3D heart analysis using conventional 2D ultrasound technologies. Jessica will be responsible for translating the Company's business objectives into marketing strategies that drive revenue. With 15 years of experience in marketing for technology-based companies, most recently in the medical device industry, she brings a proven track record in the development and management of comprehensive marketing campaigns, which integrate a strategic approach to public relations, social media, conferences and events.

On November 5, 2018 the Company announced that the University of Chicago Medical Center in Chicago, Illinois had ordered the VMS+ complete heart analysis system. Spearheaded by Dr. Roberto Lang, the VMS+ system will be installed and used for 3D volumetric analysis of the whole-heart. With the recent market clearance from the FDA, the University of Chicago will be one of the first sites to evaluate and publish on the performance of the VMS+ system vs MRI for all 4 cardiac chambers. Dr. Lang is a Professor of Medicine and Director of the Non-invasive Cardiac Imaging Laboratory at the University of Chicago. He is an internationally renowned cardiologist and specialist in echocardiography. Dr. Lang uses his vast knowledge of cardiac imaging techniques to evaluate patients with a wide variety of heart conditions, including heart failure and valve disease.

On November 12, 2018, the Company announced that St. Michael's Hospital in Toronto, Canada had ordered the AI based VMS+ complete heart analysis system for use in clinical evaluations of cardiac patients. Dr. Howard Leong-Poi and Dr. Chi-Ming Chow are spearheading the VMS+ acquisition. Dr. Leong-Poi, is the Head of the Division of Cardiology at St. Michael's Hospital and a Clinician Scientist in the Keenan Research Centre for Biomedical Science. Dr. Chow is the Director of the Echocardiography Lab and has expertise in the development of innovative technologies in the practice of echocardiography. Both have clinical interests in cardiac imaging in ischemic heart disease and valvular heart disease.

On November 14, 2018, the Company announced it had entered into a Contribution Agreement with the Government of Canada. The National Research Council of Canada Industrial Research Assistance Program (NRC IRAP) will provide both advisory support and conditional funding to share the costs of a project designed to accelerate the further development of the Ventripoint VMS+ system's next-generation products. The goal of the project is to extend the current technology for advanced visualization extracted from 2D ultrasound images of the heart to construct and visualize 4D from 2D ultrasound images. 4D is the real time display of the beating heart in a 3-dimensional view, with quantification of the movements as well as 2D measurements. The project also aims to include the addition of advanced measurements for Wall Motion Velocity and Left Ventricle Mass, to further aid the clinician in assessing the cardiac disease state. Currently, 4D products are available in the marketplace and while they have improved significantly, they still are only able to get useable images in 60% of people for the basic heart analysis and, therefore, are only used for research purposes. The VMS+ system's accuracy matches that of the MRI, the gold standard, providing a significant opportunity for the unique 4D VMS+ system in the market. For the clinician, the Ventripoint solution of 4D display will provide additional information about the motion of the different chambers of the heart throughout the cardiac cycle, quickly and reliably. The provision of both quantitative and qualitative information essential for complete assessment of the cardiac condition is the major goal of this project.

On November 19, 2018 the Company announced it had extended its product line to include the VMS+ (software only for 3D). This product is also approved for sale in Europe, Canada and the USA. The Company is building a sales and distribution team to capitalize on these product expansions.

On November 20, 2018 the Company announced that Dr. Kai Thorsten Laser, an internationally renowned pediatric cardiologist at the HDZ NRW Heart and Diabetes Center in Germany, had begun using the VMS+ (software only) clinically for analysis of the left ventricle using 3D echocardiograms. HDZ NRW, a hospital specializing in the treatment of cardiac, vascular and metabolic diseases has already implemented the VMS+ software for analysis of the right ventricle. Now that the software has been approved for all 4 chambers of the heart, the hospital will be using the Ventripoint VMS+ system for left ventricular volume analysis, particularly for their pediatric patients.

On November 29, 2018, the Company announced that it will be exhibiting at EuroEcho 2018, the annual congress of the European Association of Cardiovascular Imaging to showcase the next-generation VMS+ System. With nearly 4,000 healthcare professionals from over 90 countries around the world, EuroEcho is one of the world's largest cardiovascular imaging congresses and is a premier place to meet with world-renowned global experts in the field of cardiovascular imaging. Ventripoint will be exhibiting in booth D400 at EuroEcho held in Milan, Italy from December 5<sup>th</sup> – 7<sup>th</sup> providing hands-on demonstrations of the next-generation VMS 3.0 system.

On December 8<sup>th</sup> at 8:30 AM, Dr. Shelby Kutty of Nebraska Children's Hospital will be presenting a poster in section P1694 on a comparative study performed with the VMS+ System "Application of knowledge-based reconstruction to three-dimensional echocardiography and comparison with semiautomatic border detection method for evaluating ventricular function". The next-generation VMS3.0 system is designed to provide a streamlined approach for volumetric measurements and ejection fractions for all 4 chambers of the heart from standard 2D echo images.

The Company previously announced (see NR, Nov. 11, 2017) the invention of a small, low-cost location device, which tracks the ultrasound probe's position and orientation in 3-dimensional space. The new design eliminates the need for patients to remain perfectly still during image acquisition and improves the workflow of the VMS+ through a more intuitive user interface and a smaller footprint.

The VMS 3.0 will allow the Company to provide the VMS+ inexpensively to customers and charge for the reconstruction of the study. This subscription model is the trend in imaging studies as it becomes more cost effective to outsource the analysis than maintain the expertise to analyze difficult and technically-challenging cases, especially in small and medium-sized centers. The Company intends to offer both a capital purchase option as well as the subscription option to customers starting in 2019.

Since 2007, the Company has completed a number of equity and debt financings to fund its technology development and commercialization activities, and will likely continue to seek additional investments from both public and strategic investors.

## **Corporate Strategy**

The overall strategy is to have a suite of products available to allow customers with existing 2D and 3D ultrasound machines to purchase the VMS+ and then upgrade to the integrated 2D-VMS machine when they are ready to buy new 2D ultrasound machines. The normal average life cycle of a cardiac ultrasound is 5-7 years and many are now past the end of their useful life. Thus, there is now a large emerging opportunity to sell integrated 2D-VMS machines as replacement machines. Ultimately, the strategy will be to sell the VMS+ (software only for 3D) analytical package for 3D ultrasound as the 3D spatial data is already embedded in the 3D scans and so no additional hardware is required. There would still be a need for the 2D VMS products in about a quarter of the patients and so those cardiologists wanting to use 3D would need to buy both products to effectively and efficiently examine all their patients. The 3D ultrasound machines currently only provide readable images in about 50% of patients

and so are not used clinically for global heart measurements. The Company has now created a software-only module for the VMS+ for analysis of 3D echocardiograms. A major centre in Germany has purchased this product and will be publishing shortly on its application in pediatric cardiology (see NR November 20, 2018).

The Company still believes that the KBR approach is the best approach to use in building a semi-automated analysis package for 3D scans. To this end, the Company previously announced (see NR, March 19, 2018) a collaboration with Ryerson University to use its Artificial Intelligence (AI) expertise to develop a software engine to automatically detect all four chambers of the heart in standard echocardiographic views. On August 13, 2018, the Company announced that the university researchers had completed an initial prototype of the AI engine. This software can be used to detect the end systolic and end diastolic frames in cardiac video clips in number of different views. In initial testing with images provided by the Company, results were impressive with an up to 90% accuracy rate in identifying cardiac ultrasound views. If successful, this will reduce time spent on analysis and training and allow sequential exams conducted by different users to be compared with confidence. Even today, the comparison of sequential exams is difficult to interpret due to operator variability in image acquisition and this makes analysis, and therefore disease progression, hard to quantify. Automated analysis will ensure comparability between sequential studies.

The Company has appointed experts in ultrasound and biomedical commercialization. In November, 2015, the Company appointed Dave Willis to the Board of Directors. Mr. Willis is an expert in the development and international sales of ultrasound equipment. Until recently, he was Vice President Competitive Strategy and Product Innovation at SonoSite-Fujifilm Ultrasound, where he was responsible for design input, launch and global training of 4 major product releases. He also served as Vice President of Sales and Marketing the Americas for Ultrasonix Medical Corp, where he managed sales forces in Canada, U.S.A, and South America. Mr. Willis had been with SonoSite Ultrasound previously as Vice President of General Imaging Business Unit, where he helped grow sales to \$65 million, and as Director of Product Marketing. In the 1990's, he had positions with ATL Ultrasound as Director of Clinical Marketing, Manager of Clinical Investigations, Senior Clinical Specialist, International Sales Specialist and Applications Specialist, where he managed a distribution network in Asia.

In Q1 2016, Dr. Don Segal was appointed as a Director of the Company. Dr. Segal is an entrepreneur with a successful history of starting companies both in the private and public sector. With approximately 40 years of experience in the healthcare industry, he has managed several start-up companies through to commercialization. He is currently the Chairman and CEO of United Biopharmaceuticals Inc. Previously he founded Joldon Diagnostics and spearheaded its amalgamation with Intercon Pharma and Helix Biotech to form Helix BioPharma Corp (TSX:HBP), where he was Chairman and CEO. During his tenure, the Helix BioPharma was listed on the TSX and NYSE and raised significant funding from capital markets to support product commercialization. Dr. Segal's first company was Radioimmunoassay Inc. (RIA Inc), which was sold as a private company. Dr. Segal has a Ph.D. in Medical Sciences from the University of Guelph.

On July 1, 2017, Mehran Mehrtash was appointed as Vice President, Worldwide Distributor Sales. Mehran Mehrtash is an experienced international executive in the healthcare industry. He most recently served as the Vice President/General Manager of the Global Distribution Division for Sonosite Inc. In this capacity he led global indirect operations including independent distributors in emerging markets in Latin America, Europe, Africa, Asia, and the Middle East as well as Fujifilm subsidiaries in China, India and Japan. From 2007 to 2015 Mr. Mehrtash was based in Singapore where he led the Asia Pacific

& Middle East region with full P&L responsibility and annual revenue growth of 20%. Prior to that Mr. Mehrtash worked for ConvaTec Inc, a former division of Bristol Myers Squibb during which time he managed all direct and distributor commercial and operational priorities for the Asia Pacific region, including: Greater China, South Korea, India and the ASEAN markets. Among many accomplishments, Mr. Mehrtash led the establishment of Sonosite's regional headquarters in Singapore and a direct subsidiary in South Korea, as well as rapid expansion of the ConvaTec China team, which grew from a total of 10 staff members in 2008 to more than 100 in early 2011, resulting in a tripling of its annual sales. The Asia Pacific regional leadership teams he established comprised of sales, marketing, and functional support staff in human relations, finance, regulatory, and operations.

On August 1, 2017, Desmond Hirson was appointed as Vice-President, Development and Operations and in December, 2017 Desmond was promoted to the role of President. Desmond is a seasoned executive and has over 20 years of experience in commercializing medical devices and managing product development, manufacturing operations, and regulatory and quality assurance. He has had multiple successes in start-up ventures including three exits at Sonosite Inc, VisualSonics and DICOMIT Inc. Desmond joined VisualSonics in 2003 as Vice President, Engineering, and led a development team to commercialize novel ultrasound technology from prototype to market success in cardiovascular, cancer and other areas of preclinical research that also resulted in ground breaking clinical applications. VisualSonics was purchased by SonoSite, a Seattle based ultrasound company in 2010 followed by the sale of SonoSite and VisualSonics to FUJIFILM of Japan in late 2011. At that time Desmond became Vice President Engineering and General Manager of FUJIFILM VisualSonics. Prior to this Desmond developed ultrasound technology for hospital PACS systems, ultrasound image processing and 3D visualization. Desmond holds a master's degree in electrical engineering and is co-inventor on a number of patents.

On December 12, 2017, the Company announced that it had appointed Dr. Alvira Macanovic as the Manager of Regulatory Affairs and Quality Assurance, received the ISO60601 safety certificate for the VMS+ device and moved its Development and Manufacturing Centre, as well as its Corporate Offices.

Dr. Macanovic has over 10 years of experience in pharmaceutical and medical device related industries where she has worked with researchers, start-ups, SMEs, and multi-national companies to commercialize technologies in multiple therapeutic areas. She has developed regulatory and quality strategies and plans to deliver high quality, safe, and reliable medical device products to market efficiently and cost-effectively. Most recently, as Director of Regulatory Affairs and Quality Assurance at a medical imaging company, she oversaw all aspects of the regulatory affairs/quality operations and activities for the successful launch of their products in Canada, the United States, and China. Previously, Dr. Macanovic worked for a non-profit organization supported through the Centres of Excellence for Commercialization and Research to commercialize medical imaging and digital pathology technologies. She obtained a Bachelor of Science in Biochemistry from McGill University and a PhD in Chemistry from Concordia University.

On January 10, 2018, the Company announced the appointment of David McPhedran as Director of Sales for North America. Dave McPhedran is an experienced leader in the healthcare industry. Previously, he was Director of Sales for imaging in Western Canada for Siemens Healthcare, where his team achieved sales targets of \$35M per year. Dave has also worked for Becton Dickinson and Johnson & Johnson in sales and marketing. He received his Bachelor of Science degree from the University of Waterloo.

On February 6, 2018, the Company announced that Dr. Andriy Shmatukha has joined the Ventripoint team as software developer to advance the Ventripoint products and technology. Dr. Shmatukha is a qualified network administrator with over 18 years of medical device R&D experience with emphasis on diagnostic cardiac imaging, including the development of image analysis algorithms and associated software. At his tenure at GE Healthcare he was responsible for quality assurance of clinical trials for medical software. He is an inventor on multiple patents in image analysis algorithms and device hardware. As a research engineer at Sunnybrook Health Sciences Center (Toronto, Canada), he developed DICOM application software to manipulate medical images to allow them to be analysed and stored in a hospital Picture Archiving and Communication Systems (PACS) environment. At Utrecht University Medical Center (Utrecht, The Netherlands), he developed MRI imaging procedures and image analysis algorithms for real-time MRI guidance of minimally-invasive thermal therapies.

On March 14, 2018, the Company created a Business Advisory Committee (BAC) and appointed Dr. Samuel Schwartz as the inaugural Chairman. The BAC will provide senior management and the Board of Directors with strategic advice on matters including, but not limited to, financing alternatives and opportunities, market opportunities, human resource insights, and new technology perspectives, in addition to carrying out special assignments. Sam is the founder of The Strategic Law Group. He previously was the Managing Partner of the Toronto office of DLA Piper Canada LLP, where he practiced in the areas of corporate/commercial, corporate finance, structuring, and securities law, including merchant banking and public and private company transactions. His diverse client base included Canadian and foreign companies involved in the life sciences, biotechnology, and computer hardware and software. Sam has regularly assisted established as well as start-up companies in accessing the capital markets both in Canada and the United States. In addition, he has assembled professional teams to assist Canadian companies in their business development efforts worldwide. Among Sam's community involvements, he served on the Strategic Planning Committee of the Baycrest Centre for Geriatric Care; the National Board of Directors of the Canadian Friends of Hebrew University; the National Campaign Cabinet of the Canadian Cancer Society; and the Board of Directors of Mount Sinai Hospital Foundation. He also served on the Board of Governors of York University and is presently a Life Honorary Governor of the University. Sam received his JD and LLB from Osgoode Hall Law School of York University and was called to the Ontario Bar in 1974 and the Alberta Bar in 1978. Previously, he received an MA degree from York University and a BA degree from the University of Toronto. In 2010, he was recognized by Osgoode Hall Law School by being awarded a Gold Key for Outstanding Achievement. In 2015, he was awarded an Honorary Doctorate Degree from York University for Outstanding Contributions to the Canadian Community.

On May 22, 2018, the Company announced the appointment of Jim Graba BSc, RDCS, FASE, as Application Specialist and Chief Trainer. Jim will take the clinical lead in the deployment and training of customers. In addition, he will provide product strategy and direction for the development team. Jim previously held positions in the healthcare industry, including Chief Cardiac Sonographer at the Toronto General Hospital and Manager of Echocardiography at the University Health Network. His decades of experience make him keenly aware of workflows and methodologies within the clinical and research Echo environments. He is well known as an innovator with multiple medical publications and as mentor in the Echo community. His commercial experience with the development and deployment of other ultrasound technologies with VisualSonics, as Product and Applications Specialist, makes him exceptionally well qualified to assist in evolving the VMS+ to have even broader applications. Jim is also a certified Health Informatics professional and will be key in installing Ventripoint products into the sophisticated digital environment of hospitals and institutions throughout the world.

The Board elected to move the Company's development operations to Canada to begin the creation of the 4-chamber system as well as to upgrade the hardware and software for the VMS to be ready for the 4-chamber application. Accordingly, the Company established a new facility in Toronto, Canada in early 2016. There is an excellent pool of software and hardware engineers in Toronto to draw upon for the 4-chamber project at more reasonable cost than the Seattle location. In addition, there are government grants available for development projects.

The Company also elected to hire outside vendors for the 4-chamber development. Consequently, it hired Precision Image Analysis to build the new right atrium (RA) and left atrium (LA) catalogues using its internal image library. Over many years, the Company has amassed an excellent cardiac image library with both MRI and ultrasound image files from patients with a wide variety of cardiac conditions. This is a very valuable resource that anyone wishing to build catalogues would need to replicate. Consequently, the Company has been able to produce the new catalogues more quickly.

The Company was able to extend its license for the KBR technologies with the University of Washington to include the atria. The building of new catalogues requires an iterative process of tracing the heart chambers and then verifying the accuracy of the tracings using the KBR algorithm and then retracing any images that have motion artefacts and other inaccuracies. The Company is pleased to report the catalogues have been created and tested for accuracy and been shown to yield results equivalent to MRI analysis. The Company has established relationships with two clinical centres to advise it on the development and testing of the 4-chamber user interface and catalogues. The clinical evaluation continues with a focus on optimization of scanning protocols and work flow.

The Company also hired Walled Networks to assist it in the software and hardware upgrades. They redesigned the VMS+ to be manufactured more easily, while reducing the foot print and weight of the machine. They also made the VMS+ more mobile and upgraded the computer hardware to current standards and to work with the newer, higher-resolution, digital 2D ultrasound machines. This was necessary as many of the components for the VMS were no longer available and newer ultrasound machines have evolved as well. The result is a much improved machine, which can be mass produced. The design of the VMS+ hardware has been finalized and regulatory approval received in Canada, Europe and the USA. The VMS+ has received ISO60601 certification, which is the international standard for laboratory equipment to be used in a medical setting.

In Q4 2015, the Company entered into an agreement with Lishman Global Inc. to set up a self-financing joint venture in China to develop an integrated VMS-ultrasound machine, as well as to manufacture and market existing and new VMS machines in China. The Company retains all rights to market the Chinese-manufactured machines outside of China.

On September 23, 2016, the Company reported that a joint venture has been formed in China called Ma'anshan YuTian Medical Technology Co. Ltd ("YuTian Technology"). The first investments are complete and YuTian Technology is fully capitalized to meet its goals of product manufacturing, product development, certification, sales and marketing and the achievement of profitability within two years.

On October 31, 2016, the Company announced it had received payment from YuTian Technology to purchase the first batch of components to begin the manufacturing process of the VMS+ heart analysis units in China. The first machine was constructed in Q4 2016 and an additional 3 machines were fabricated in Q1 2017. Two machines will be used to facilitate the submission to the Chinese FDA for marketing approval and obtain appropriate certifications for medical use in hospitals in China including ISO60601 (China version). YuTian has applied to the Chinese FDA for approval of the VMS+ with RV analysis software and expects to have marketing approval in 2018. The other two machines will be used

to demonstrate the machine to leading cardiologists and distributors in China. Our Chinese partners are establishing a distribution network for medical devices for all of China.

## **Product Development**

The Company continues to look for ways to make the VMS system easier to use, expand its capabilities and increase its value. Initially thought to be years away, Ventripoint has completed the development of chamber-specific catalogues. All the VMS analytical products; 2DE, 3DE or CMR use the same chamber-specific catalogues to generate volumetric measurements. The VMS+ for 2D and 3D images is approved for sale in in Canada, Europe and the USA.

### **2D Echocardiography**

The Company recently upgraded the hardware for 2DE. Its new and improved features include:

- a smaller cart which provides increased mobility,
- a new keyboard and viewing screen for a more ergonomic design,
- upgraded hardware to support wireless network connectivity,
- upgraded hardware to interface with new high-resolution, digital, 2D-ultrasound machines,
- VPN connection to the server to reduce the need for the hospital IT department during installation and ongoing functionality,
- upgraded software to facilitate the deployment of the whole-heart software suite,
- updated software to bring it up to current standards for hardware and software libraries.

The Company is approved to manufacture this new VMS+ (hardware and software for 2DE) model in Canada for worldwide use.

The Company is also working on a new model of the VMS hardware and software, the VMS 3.0. This model has been designed to improve workflow, lower the size, lower cost and incorporates a new position location system (see NR, Nov. 11, 2017) which allows for patient movement during image acquisition. A prototype has been built and is undergoing final functional testing which is expected to be completed by the end of 2018. The Company will be demonstrating the VMS 3.0 at the EuroEcho conference in early December (see NR, Nov. 29, 2018). It is expected to be approved in 1Q19 and first sale in 2Q19.

The Company has identified additional improvements that can be incorporated in the next version and will immediately begin development of the next-generation device. One of these improvements would be the ability for advanced visualization extracted from 2D ultrasound images of the heart to construct and visualize 4D from 2D ultrasound images (see NR Nov. 14, 2018). 4D is the real time display of the beating heart in a 3-dimensional view with quantification of the movements as well as 2D measurements. The project also aims to include the addition of advanced measurements for Wall Motion Velocity and Wall Mass. Another improvement will be the use of AI to automatically identify the views and select certain landmarks (see NR Mar. 19, 2018 and Aug. 13, 2018). An additional improvement will be the use of the DICOM file generated by the 2D ultrasound machine to provide the images to be analyzed. This will greatly simplify the VMS hardware and lower the cost of the equipment significantly. This will improve margins and make it possible to supply a VMS machine for every 2D ultrasound unit in an imaging service.

The Company actively seeks ideas for improvements to its products from its customers and leading cardiologists.

### **3D Echocardiography**

The VMS technology has been shown to provide analysis of 3D ultrasound images of the right ventricle with the same accuracy as MRI (see NR Jul. 7, 2014). The development team has completed the development of the VMS+ (software only) analytical package for all 4 chambers of the heart to be used with 3D echocardiograms. This is now ready for sale and the first VMS+ (software only for 3D) has been purchased by a leading heart centre in Germany, which will be verifying the accuracy of the VMS+ (software only for 3D) for the left ventricle (see NR Nov 20, 2018).

The current use of 3DE in cardiology is for research purposes and for isolated structures of the heart, such as valves. The Company believes that the VMS approach can overcome the limitations of 3DE concerning coverage and image quality and provide more accurate volumetric functional assessments. Nevertheless, 3D echocardiography will not be used extensively clinically until the image quality improves and provides readable studies 70-80% of the time. The major large OEMs continue to spend extensively on advancing the hardware. The VMS-3DE is ready now to analyze these image sets. We will continue to research automation of the analysis while we wait for better 3DE machines to be developed.

The further development of such technologies is consistent with Ventripoint's corporate mission of being a leader in providing medical products that use AI to enhance the productivity, accuracy and consistency of cardiac measurements. The benefits of this technology can also be extended to other modalities and imaging technologies, such as MRI and CT, to further expand the use of AI in the field of medical imaging.

### **Commercialization – Strategies and Implementation**

The successful launch and adoption of a new medical device requires acceptance by multiple groups. Among the most fundamental is a credible independent validation of meritorious use of the VMS in clinical-care settings. It is essential that the ultimate payers for healthcare (e.g. government, third party insurers) receive the appropriate professional recommendations with supporting justifications and verify the device represents a medically effective and financially efficient tool that fits within the healthcare industry's complex set of business and patient-care needs.

The Company believes the support of thought leaders is the first building block to gaining the endorsement of the product. Accordingly, the Company has collaborated with leading echocardiologists and institutions in the field of Congenital Heart Disease (CHD), PAH and other heart conditions. Establishing luminary sites across multiple geographies has and will enable the Company to best select those studies that address clinically relevant challenges and solidify the medical benefits of its VMS system in clinical settings, as well as to disseminate the study results more broadly. To build awareness, VMS deployments are designed to produce publications in leading medical journals and presentations at conferences. When possible, the Company attends the conferences where the results of these clinical studies are being first presented to the medical community. The Company has been successful in having a number of independent studies published.

## Independent Clinical Studies

1. A multicentre group from the University of Chicago and Elisabethinen Hospital in Linz, Austria presented a study entitled “Three-dimensional Modeling of the Right Ventricle from Two-Dimensional Transthoracic Echocardiographic Images: Utility of Knowledge-Based Reconstruction in Pulmonary Arterial Hypertension”. Dr. Lang from the University of Chicago and past President of the ASE stated; “*The Ventripoint 3D system provides reproducible measurements of RV volumes in pulmonary arterial hypertension patients. The clinical accuracy of VMS helps obtain valuable information that can impact patient care*”.
2. A group led by Dr. Laser from the Heart and Diabetes Center NRW (HDZ NRW), Bad Oeynhausen, Germany reported on the first use of the prototype VMS-4DE software, which analyses 4D ultrasound cardiac images, in a paper entitled; “*Right ventricular volumetry in healthy children and young adults by RT3DE - New axis, new quantification tool with promising results*”.
3. A group led by Dr. Soriano from the Seattle Children’s Hospital reported on their early experiences with the VMS in a number of children with a broad range of heart problems in a paper entitled; “*Echocardiographic 3D Reconstruction Accurately and Precisely Measures Right Ventricular End Diastolic Volumes: Preliminary Pediatric Experience in a Single Institution*”. Dr. Soriano commented “Our ongoing research experience with the Ventripoint equipment has been very positive and we look forward to applying it routinely once it is available for clinical usage in the USA”.
4. The cardiology group from the University of Chicago, led by Dr. Roberto Lang, published a paper entitled “*Three-Dimensional Modeling of the Right Ventricle from Two-Dimensional Transthoracic Echocardiographic Images: Utility of Knowledge-Based Reconstruction\* in Pulmonary Arterial Hypertension*” in the Journal of the American Society of Echocardiography, Volume 26, Issue 8 , Pages 860-867, 2013. The paper concludes: “Three-dimensional reconstruction of the RV endocardium from 2D transthoracic echocardiographic images obtained in patients with Pulmonary Arterial Hypertension (PAH), as accomplished by Knowledge-Based Reconstruction (KBR), is feasible, accurate, and reproducible”.
5. Dr. Johannes Schwaiger of the Department of Cardiology at Royal Free Hospital in London lectured at the 13<sup>th</sup> International Pulmonary Hypertension Forum in Lisbon on his experiences using the VMS to verify a significant change in RV ejection fraction after novel targeted treatments, which resulted in significant improvements in patients with PAH in a session entitled “*Progress and future challenges in the management of PAH*”.
6. Dr. Henrik Brunand and his group at the Rikshospitalet University Hospital in Oslo, Norway, published a paper in the Congenital Heart Disease Journal entitled “*Right Ventricular Volumes Assessed by Echocardiographic Three-dimensional Knowledge-based Reconstruction Compared with Magnetic Resonance Imaging in a Clinical Setting*”. The paper reports on patients with Congenital Heart Disease who had undergone pulmonary valve replacement and found excellent feasibility (97% of patients could be assessed) with VMS and clinically useful correlations with MRI for RV volumes. The paper concludes with the comment “*Knowledge-based reconstruction [VMS] may replace MRI measurements for serial follow-up...*”
7. A group from L’hôpital Universitaire Necker-Enfants Malades in Paris, France had published a paper entitled: “*Knowledge-based 3D reconstruction compared to MRI for evaluation of right ventricular volumes and function in congenital heart diseases affecting the right ventricle*” in

*Archives of Cardiovascular Diseases*, Volume 107(9), 491-500. For the first time, along with a wide range of patients with congenital heart disease (CHD), patients with all stages of repaired Hypoplastic Left-Heart Syndrome (HLHS) were studied. The VMS allowed for repeated evaluation of these very ill children, while MRI continues to be very difficult and dangerous to perform. This is of particular concern in these HLHS patients. The paper concludes: “3D-KR ... provides accurate and reproducible measurements of RV volumes. This new technique can be used as an accurate routine tool to assess RV function in CHD”.

8. A paper entitled “Accuracy and Test-Retest Reproducibility of Two-Dimensional Knowledge-Based Volumetric Reconstruction of the Right Ventricle in Pulmonary Hypertension” was accepted for publication in the *Journal of the American Society of Echocardiography*. The full article is available at <http://www.onlinejase.com/article/S0894-7317%2815%2900142-X/references>.

The study design compared the accuracy of the measurements performed by the cardiologists who independently performed an echocardiogram on the same patient and then analyzed the scans. This “test-retest” design is unique in that a majority of studies comparing measurements performed by different individuals are typically completed with the observers using the same echocardiographical images. This type of study method reflects the real world clinical use of echocardiography, where patients receive echocardiograms on different days performed by different cardiologists and they are used to assess if changes in heart function have occurred. An accurate, reproducible procedure is absolutely necessary to make therapeutic decisions.

This clinical study demonstrated that the VMS analysis of the right heart is reproducible between operators. This means that the cardiologist can trust previous test results regardless of the examiner, so long as the echocardiogram was analyzed using the VMS. Further, the study determined that results produced by VMS were more accurate and reproducible than Fractional-Area Change, which is one of the methods of estimating right-heart function recommended by the ASE imaging guidelines.

9. The cardiology group at Royal Free Hospital in London, UK published a study entitled “Two-dimensional knowledge-based volumetric reconstruction of the right ventricle documents short-term improvement in pulmonary hypertension” in *Echocardiography*, volume 34, pages 817–824. This study confirms the ability of the VMS Heart Analysis System (referred to in the paper as “two-dimensional knowledge-based volumetric reconstruction” or “2DKBR”) to follow patients with enlarged right ventricles (RV) and accurately measure small but medically-significant changes in volume and function. This ability to monitor clinical outcomes shortly after the initiation of therapy is important to determine if the therapy is working well or if a new therapeutic approach is required. The VMS detected the remodelling of the RV to reduce its size in patients who improved and an increase in RV size in patients with worse clinical outcomes including death.

“Ventricular remodelling in PAH can be differentiated into two patterns: adaptive remodelling with concentric hypertrophy and preserved function, and maladaptive remodelling with eccentric hypertrophy and worsening function. Our study shows that within several months a change from one pattern to the other can occur with medical therapy,” stated the authors.

The publication concluded; “2DKBR can be reliably used in a busy clinical setting to follow-up right-ventricular indices in pulmonary hypertension...”

The need for reliable quantification of all 4 chambers of the heart is emerging as doctors cannot rely on the results from previous exams due to the large variations between observers using conventional

analysis techniques. The VMS+ has excellent reproducibility as published in the above-mentioned study and others. Looking at the evolution of the patient's heart (remodelling) is a better way to understand the particular type of heart disease but is not done now due to the variability from exam to exam. This ability to standardize the analysis within a hospital, as well as between hospitals is becoming more important as patients are admitted at different sites. The need to "redo" cardiac exams is a costly and unnecessary process if the VMS+ was used.

## **Sales and Marketing**

The Company is building a sales and distribution team for global sales and marketing. The Company has reviewed its sales approach and has met with a number of existing and potential customers to determine the highest value propositions in defined cardiac care settings. Ventripoint has identified many settings where the VMS is regarded as critical to providing the best cardiac diagnosis and monitoring. The Company has been contacting known experts in these application areas to further understand the need and create initial sales and partnerships. This process is ongoing. The Company has received 5 orders (see NRs: Feb. 21, 2018; Jun. 4, 2018; Nov. 5, 2018, Nov. 12, 2018; Nov 20, 2018) with 2 from Canada, 2 from USA and 1 from Europe. Each of these new users are recognized leaders in cardiac care and will be using the VMS+ to expand the application of the VMS+ to inform the best treatment path to be taken by patients. There are an additional seven hospitals currently indicating they will order a VMS+, subject to budget approvals. The Company also has a number of hospitals requesting an on-site demonstration of the equipment, which is now possible using the VMS 3.0 prototype, which is easily transported and setup.

While initially markets in Asia and regions in the Middle East were viewed as good places to build awareness, it became obvious that these regions would wait until leaders in the field in developed countries were using the VMS+. On November 15, 2017, the Company announced it had signed a memorandum of understanding (MOU) to establish a partnership with the SEED Group, a group of diversified companies owned and chaired by The Private Office of Sheikh Saeed Al Maktoum of Dubai, United Arab Emirates. The partnership was initially to focus on making hospitals, doctors and officials aware of the unique features of the VMS+ through research, conferences and opportunities designed to demonstrate its population health applications, however the Company has put this initiative on hold while it focuses its efforts on sales and research in Canada, Europe and USA. The Company will restart discussions with potential distributors in Iran, Singapore, Thailand, U.A.E. and Saudi Arabia, when it has significant sales in western countries.

An experienced marketing person has been hired (see NR Oct 21, 2018) and the Company has put a lot of effort into preparing for the EuroEcho Conference (see NR Nov. 29, 2018), where the VMS 3.0 will be available for live scanning and analysis by the conference attendees. Attendees at the conference come from 90 different countries and it is an excellent way to meet potential customers.

The Company continues to interview leading cardiologists to identify specific cardiac conditions where clinical studies would verify the need for the VMS. These experts have identified, uncontrolled hypertension (50 million people in the USA), normal and high-risk pregnancies, cancer chemotherapy, congenital heart disease and technically-difficult imaging (20-30% of all echocardiograms) as highest-value applications.

The Company commissioned a market survey for Canada. The study shows there were ~150 cardiac ultrasound machines purchased in each of the last 5 years. Data from a number of one-on-one interviews with cardiologists confirmed the need for better heart-chamber quantification in cancer patients,

paediatrics, technically-challenging patients, where contrast-media is routinely injected, and in high-risk pregnancies, as well as providing suggestions of other areas of application where current methods are either unreliable or too costly and so are not done. The Company has focused on building support for 3 application areas.

## **Current Focus for Clinical Applications**

The Company has been reviewing other applications where the volume and function of different heart chambers have been shown in recent studies to correlate with the progress of heart disease or medical interventions. The current foci are:

1. 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 Company intends to contact cardiologists within cancer centers to determine the need to accurately determine RA and RV size and function during and after cancer therapy using the 4C-2DE-VMS+.

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.

The Company announced on June 4, 2018, only a few weeks after obtaining FDA clearance, that MD Anderson Hospital had ordered a 4C-VMS+ to use for routine clinical assessment of oncology patients to determine cardiac changes during and after treatments. The machine has been shipped to Houston and will be installed shortly, now that modifications to the hospital’s image archiving system have been completed. 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. The hospital sees approximately 1.5 million patients a year and performed 575,000 imaging exams in 2017.

2. 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 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). 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 parts become recognizable. The Company believes it can significantly reduce the use of contrast media, which would save time, money and patient discomfort.

On February 21, 2018, the Company announced the installation of the VMS+ 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 study will address technically-difficult patients and the ability of the VMS+ to reduce the use of contrast media. In 10-20% 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. On July 17, 2018, the Company announced the study had begun.

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.

3. High blood pressure or hypertension continues to be a major risk factor for heart attacks and other cardiac conditions. A study published in the New England Journal of Medicine (the number one clinical journal) reported "The number of persons with hypertension is increasing, and an estimated 44% of U.S. adults with hypertension did not have this condition under control in 2014. The definition of hypertension has recently been revised and narrowed, so there are 100 million people in the United States with hypertension, of which 44 million are not adequately treated. Thus, there is an enormous potential for improving population health by expanding treatment and improving control...not only would prevent about 56,000 cardiovascular events and 13,000 deaths from cardiovascular causes annually but also would result in \$5B in cost savings."

The volume of the left atrium (LA) is a direct indication of the degree of control of blood pressure over an extended period of time and is correlated to mortality with larger volumes indicating earlier death. There is a large opportunity here to measure LA volume and identify the 44% of people with uncontrolled hypertension. Such a screening process could easily be done with the 4C-2DE-VMS+ using conventional 2D ultrasound. Every cardiologist has access to a 2D ultrasound service or machine and so could begin this cost-reduction program immediately. The

key is accurate, reliable and rapid assessment of LA volume. The Company is discussing this project with leading cardiologists.

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

### **Marketing Efforts**

This VMS validation and awareness campaign continues to engage the support and endorsement of opinion leaders and to position VMS for broad acceptance by clinicians in Canada, Europe and in the USA. A significant effort is spent at medical conferences where large numbers of echocardiographers gather to hear the latest best practices. The Company has exhibited at:

- The American Society for Echocardiography annual conference, June 22-26, 2018 in Nashville, Tennessee, and identified a number of potential customers. The conferences had a combined attendance of 3,000 attendees from almost 50 countries. The sales team is following up with these contacts and reaching out to 300 clinical centers, which have a profile of patients where the VMS+ would provide significant benefits to their cardiac service. Capital purchases require a long process for budget approval, as well as signoff by a number of hospital departments, such as bioengineering and IT, before a purchase order is generated.
- The 20<sup>th</sup> Annual Canadian Society of Echocardiography conference in Toronto, in April, 2018. The gathering is attended by cardiologists and sonographers, and is the largest single gathering in Canada with over 600 attendees. This was an opportunity to showcase our latest VMS+ system, which demonstrated volumetric measures for all 4 chambers of the heart. This new system was well received by clinicians who appreciated the value of ultrasound 3D visualization with fast and accurate measurements, equivalent to the gold standard MRI for all heart chambers. High profile cardiologists from all the main cardiac centers in Canada visited the booth and expressed interest in this unique product. This gave us the opportunity to engage with potential customers and to collect prospects and leads to contribute to our expanding sales effort.
- EuroEcho Imaging 2017 conference in Lisbon. Many leaders in echocardiography visited the booth and reviewed the new 4C-2DE-VMS+ product, which had not received CE Mark at that time. On December 15, 2017, the product received the CE Mark and the sales team is now following up with clinicians who requested additional information at the conference.
- The 27<sup>th</sup> Scientific Sessions of the American Society of Echocardiography in Seattle in 2016. There continues to be more scientific presentations on RV each year at this major congress. There were also papers on the evaluation of the LA and RV and the limitations of existing techniques.
- The American Society of Echocardiography Scientific Session (ASE) in Boston in June 2015. Cardiologists at this major conference indicated that they wanted an ability to analyze the volumes for all 4 chambers of the heart.

### **Chinese Partnership for Development, Manufacturing and Distribution**

In Q4 2015, the Company entered into an agreement with Lishman Global Inc. to set up a self-financing joint venture in China to develop an integrated VMS-ultrasound machine, as well as to manufacture and market existing and new VMS machines in China. The Company retains all rights to market the Chinese-manufactured machines outside of China. An initial investment in Ventripoint Diagnostics Ltd. of CDN\$500,000 was received by the Company and a follow-on investment of \$150,000 was received

in December 2016. The agreement anticipates an additional CDN\$2.1M will be invested by Chinese entities who will be part of the joint venture. Due to market conditions and capital on hand, the additional investment has been postponed.

On September 23, 2016, the Company reported that a joint venture has been formed in China called Ma'anshan YuTian Medical Technology Co. Ltd ("YuTian Technology"). YuTian Technology is situated in the city of Ma'anshan in Anhui Province. Shanghai YuTian is the largest shareholder in YuTian Technology and the investors include Anhui Province Hi-Tech Venture Capital Investment Co. Ltd. and Ma'anshan Economic and Development Zone Venture Capital Investment Co. Ltd. The first investments are complete and YuTian Technology is fully capitalized to meet its goals of product manufacturing, product development, certification, sales and marketing and the achievement of profitability within the next two years.

On October 31, 2016, the Company announced it had received \$240,534 from YuTian Technology to purchase the first batch of components to begin the manufacturing process of the VMS+ heart analysis units in China. Thus, the Company with its Chinese Partners is accessing the market in China. This is a major milestone as the opportunity in China continues to expand. The first machine was constructed in December 2016 and an additional 3 machines were fabricated in Q1 2017. Two machines will be used to facilitate the submission to the Chinese FDA for certifications for medical use in hospitals in China. YuTian formally applied to the C-FDA for approval of the VMS+ with RV analysis software in 2018 and expects a response in Q3 2018. Our Chinese partners are establishing a distribution network for medical devices for all of China.

The market for medical instruments in China is approximately \$7 billion per year and growing rapidly as the healthcare system is improved and extended. There are over 14,000 hospitals in China and 25% of cases are for cardiovascular disease. In the last 3 years, over 2,000 new hospitals have been built and the government health insurance now covers 90% of the population.

In addition, the Company is evaluating the integration of its technology with existing ultrasound devices and analysis packages. The Company continues to discuss with manufacturers of ultrasound equipment and analytic software the merits of combining the VMS with their systems to allow for a complete heart analysis using 2D ultrasound. The Company will disclose any agreements, to the limit possible for such commercial agreements, should they arise.

## **Company-Sponsored Clinical Trials in Support of Regulatory Filings**

The Company has completed clinical enrolment for two clinical trials in the United States which were designed to show substantial equivalency between the gold-standard MRI method and the 2D-ultrasound, VMS-2DE technique in Tetralogy of Fallot (TOF) and Pulmonary Arterial Hypertension (PAH) and has an ongoing study to examine the ability of RV analysis with the VMS tools to identify heart failure patients who will be re-admitted to hospital within 30 to 90 days.

### *Pulmonary Arterial Hypertension:*

On May 2, 2012 the Company announced that it had initiated a clinical trial in pulmonary hypertension and on October 10, 2013, the Company announced that the clinical trial achieved all its primary endpoints of accurately measuring the volume and ejection fraction of the right heart as compared to the traditional MRI analysis using the method of summation of disks. The results of the clinical trial demonstrated that the calculated parameters between right ventricular volumes computed from echocardiograms by VMS and MRI images computed with Simpson's rule were within the pre-specified

10% range for each of the mean difference and 95% confidence interval (4.8+/-1.4% for EDV, 1.8+/-1.5% for ESV, and 2.0+/-0.7% for EF).

On January 23, 2014, the Company submitted a revised 510(k) application and on March 10, 2014, the Company received clearance from the FDA to market the VMS device for use in adults with PAH in the United States. The VMS was the first ultrasound system to be cleared as substantially equivalent to MRI for right ventricle analysis.

*All Patients with Right Heart Disease:*

Right heart function remains a significant prognostic parameter for all heart disease. On May 26<sup>th</sup>, 2015, the Company announced that the US FDA had given Market Clearance for the VMS for use in all heart disease patients where RV analysis was warranted or desired.

Heart disease is the number one killer of adults, taking more lives each year than all forms of cancer combined. With more than 27 million individuals in the U.S. alone that are living with cardiac disease, there is not a single person that will not be affected by this statistic at some point in their life. This Market Clearance will greatly increase the marketability of the VMS product as it is recommended by the ASE guidelines that a RV volumetric analysis be done on heart patients.

*Tetralogy of Fallot (TOF):*

On June 24, 2013 the Company announced that the TOF clinical trial had stopped recruiting as it had achieved the goal of 75 evaluable cases. The Company has elected not to analyze the TOF study data as the RV application to the FDA was approved and allows for analysis of all patients where the RV analysis is warranted or desired.

*All Patients, All Hearts*

On March 2, 2017, the Company announced that it received a certificate for the VMS+ with 4-chamber analysis from Health Canada. On January 17, 2018, the Company announced it had received the CE Mark. On May 15, 2018, the Company announced that it received market clearance from the US-FDA for the complete heart VMS+ system. All these regulatory approvals allow the VMS+ to be used on all patients, children and adults, where the assessment is warranted or desired. There are no restrictions.

## **Regulatory**

**Canada and Europe** The Company has received Health Canada approval and has received the European CE Mark approval to market its VMS+ product and service offering.

On March 27, 2012, the Company was notified that it had received Notified Body approval to market its pulmonary hypertension application in Europe and on May 4, 2012, the Company was notified that it had received Health Canada approval to market its pulmonary hypertension application in Canada.

On April 17, 2013, the Company was notified that it had received Notified Body approval to market its NRV application in Europe. On April 25, 2012 Health Canada approved the Company's application for approval of the NRV database in Canada.

On November 11, 2014, the Company received a renewal of its European CE Mark.

On March 2, 2017, the Company announced it had received a license to market the VMS+ with the 4-Chamber analysis package from Health Canada.

On May 26, 2017, Ventripoint successfully completed an ISO 13485 re-certification audit, which is

carried out every three years, as well as a surprise audit in August, 2017.

On December 12, 2017, the Company announced it had received ISO60601 certification for the VMS+.

In January, 2018, the Company announced it had received the CE Mark for the VMS+ with the 4-Chamber analysis package.

In November, 2018 the Company concluded it had approval for the VMS+ (software only for 3D) module in Canada and Europe.

### **United States**

On March 10, 2014, the Company received clearance from the FDA to market the VMS device for use in adults with PAH in the United States. The VMS is the first ultrasound system to be cleared as equivalent to MRI for right ventricle analysis.

The Company completed an initial Establishment Inspection by the US FDA on January 8, 2015. This initial Establishment Inspection, at the Company's Bellevue, Washington location, was a pre-announced Good Manufacturing Practices (GMP) facility inspection. It was a very detailed inspection of our Quality System as it relates to Federal Regulations. The inspection reported only two minor observations, as noted on FDA Form 483, that were easily addressed.

On May 26, 2015, the Company announced that the US FDA had granted Marketing Clearance for Ventripoint's NRV catalogue, which was developed to provide right ventricular volumes of individuals being evaluated, regardless of their cardiac diagnosis. Previous submissions to the FDA required us to prove the methodology, safety, and accuracy of the entire VMS product to the reviewers, which was challenging with such novel technology. By referring to our cleared product throughout any future submissions as a Predicate Device, our path forward becomes much more predictable. This approval will also allow us to formulate additional submissions for expansion of the databases to other heart chambers.

On January 17, 2018, the Company announced it had submitted a traditional 510(k) application to the US Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) to request clearance for sale of the VMS+ whole-heart analysis system. The Company submitted the 510(k) to extend the capabilities of our current model to all 4 chambers of the heart. The submission uses the existing VMS as the predicate device and provides testing data to show that the databases for the left atrium, right atrium and left ventricle perform equally well in assessing the chamber volumes in a wide variety of heart conditions, and shapes and sizes of hearts. The volumes and ejection fraction determination by VMS+ were equivalent to MRI measurements, which is the gold standard for these types of cardiac assessments. The data also demonstrate excellent reproducibility between operators. On May 15, 2018, the Company announced it had received market clearance with the label for use for all patients where the analysis is warranted or desired. There are no restrictions on use.

In November, 2018 the Company concluded it had approval for the VMS+ (software-only for 3D) module in the USA.

## FINANCIAL HIGHLIGHTS

These Financial Highlights should be read in conjunction with Ventripoint Diagnostics Ltd.'s unaudited interim consolidated financial statements for the nine month period ended September 30, 2018 and the corresponding notes thereto.

### Capital Transactions

The fully diluted share capital of the Company as of November 29, 2018 is as follows:

	Issued and Outstanding				
	Common Shares	Convertible Debentures	Warrants	Options	Fully Diluted
Reverse takeover - 2007 Ventripoint and Diagnostics	2,432,845		7,881	115,285	2,556,011
Stock for services and payment of debt	2,764,751		405,129		3,169,880
Option grants net of expirations & forfeitures				1,010,980	1,010,980
Options exercised	72,500			(72,500)	0
DSUs exercised	150,000				150,000
Warrants cancelled/expired			(4,104,195)		(4,104,195)
Warrants exercised - 2008 - 2012	651,056		(651,056)		0
Debenture offerings - 2009 - 2014	110,000		924,514		1,034,514
Convertible Debenture offerings - 2013	234,000	728,000	689,900		1,651,900
Debenture conversions - 2014	1,000,000				1,000,000
Convertible Debenture offering - 2015	150,000				150,000
Common stock offerings - 2007 - 2014	12,088,217		4,665,897	52,635	16,806,749
Common stock offerings - 2015	7,818,181		2,480,000		10,298,181
Common stock offerings - 2016	4,666,668		4,666,668		9,333,336
Extension of convertible debentures - 2016		651,666	4,086,666		4,738,332
<b>2017 activity:</b>					
Warrants exercised	5,904,130		(5,904,130)		0
Warrants expired			(300,000)		(300,000)
Stock options granted, net of expiries/cancellations				2,708,000	2,708,000
Stock options exercised	425,000			(425,000)	0
Conversion of debentures	766,666	(766,666)			0
Cash repayment of convertible debentures		(109,000)			(109,000)
Shares for Debt offering - March, 2017	1,575,000	(504,000)	1,575,000		2,646,000
Common stock offering - March, 2017	10,779,494		10,779,493		21,558,987
<b>2018 year to date activity:</b>			0		
Common stock offering - September 2018	4,816,666		2,408,333		7,224,999
Warrants exercised	2,371,667		(2,371,667)		0
Warrants expired			(1,440,447)		(1,440,447)
Options granted				1,720,000	1,720,000
Options exercised	450,000			(450,000)	0
Options expired/forfeited				(934,400)	(934,400)
Shares issued for debt	648,397				648,397
<b>Issued and outstanding, November 29, 2018</b>	<b>59,875,238</b>	<b>0</b>	<b>17,917,985</b>	<b>3,725,000</b>	<b>81,518,223</b>

As of November 29, 2018, Officers and Directors held 3.55% of the outstanding common shares of the Company (7.8% on a fully diluted basis).

## **Capital Transactions - 2018 Year-to-Date**

### Unit Private Placement

On September 4, 2018 the Company closed the first tranche of a non-brokered private placement (the “Private Placement”) of 2,380,952 units (“Units”) at \$0.21 per Unit for total gross cash proceeds of \$500,000. Each Unit consists of one common share of the Company and one-half of one common share purchase warrant (“Warrant”), with each Warrant entitling the holder thereof to acquire one common share at a price of \$0.34 per common share for a period of 2 years after the issuance of the Warrant.

On September 13, 2018 the Company closed the second and final tranche of the Private Placement with the issuance of 2,435,714 Units for gross proceeds of \$511,499.94.

An Officer and Director of the Company subscribed for 1,500,000 Units in the Private Placement. No Finder’s Fees were paid, and the common shares and the Warrants are subject to a hold period of four months plus one day from the date of issuance.

Unlike previously issued warrants, these Warrants were treated as equity, rather than as a Derivative Liability, and were recorded as Contributed Surplus, as the exercise price of these warrants may not be adjusted under any circumstances.

### Stock option grants

Effective January 1, 2018, the new Director of North American Sales was granted 50,000 stock options of the Company, with an exercise price of \$0.25, a term of 5 years, and vest quarterly over 3 years.

On March 20, 2018, the Board of Directors granted 120,000 stock options to employees and 50,000 options to the Chair of the Company’s new Business Advisory Committee. The options have an exercise price of \$0.32, a term of 5 years and vest quarterly over 3 years.

On June 22, 2018 the Board of Directors granted a total of 1,185,000 stock options, of which 325,000 options were granted to three Officers of the Company, 235,000 were granted to employees, 300,000 stock options were granted to four independent Directors, and the remaining 325,000 options were granted to consultants. All options are exercisable at \$0.31 per share. Stock options granted to employees and Officers have a term of five years and vest quarterly over three years. Directors’ options also have a term of five years and vest quarterly over one year. Of the consultants’ options, 300,000 have a term of one year and vest immediately, while 25,000 have a term of three years and vest quarterly over one year.

On November 6, 2018, 300,000 stock options, with an exercise price of \$0.15, and expiring on June 22, 2019 were granted to consultants in replacement of the same number of cancelled options. In addition, a new employee was granted 15,000 options at \$0.17, with a term of 5 years, and vesting quarterly over 3 years.

### Shares for debt issuances

On April 5, 2018, the Company issued to the CEO 375,000 common shares of the Company in payment of outstanding back pay, accrued from 2013 through 2016, of \$120,000. The shares were issued at a deemed price of \$0.32 per common share in a Shares for Debt transaction (see NR March 29, 2018).

Also on April 5, 2018, the Company issued 28,125 shares to a consultant in payment of \$9,000 of consulting fees in common shares at a deemed price of \$0.32 and 96,774 shares in payment of a \$30,000 quarterly work fee due to financial consultants under a financial and strategic advisory services contract at a deemed price of \$0.31. The common shares issued for these transactions are all free-trading.

On June 5, 2018, the Company issued 51,724 common shares to a consultant in payment of \$15,000 of consulting fees at a deemed price of \$0.29.

On July 3, 2018, the Company issued 94,774 shares in payment of a \$30,000 quarterly work fee due to financial consultants under a financial and strategic advisory services contract. The deemed price of these shares was \$0.31.

Warrant exercises

Year to date to November 29, 2018, the Company has issued 2,371,667 common shares due to the exercise of warrants, 165,000 at an exercise price of \$0.15 per share, and the remainder at an exercise price of \$0.30, for total cash proceeds received of \$686,750. The common shares issued for these warrant exercises are free-trading.

Stock option exercises

Year to date in 2018, 450,000 shares have been issued as a result of the exercise of stock options for proceeds of \$116,400. The common shares issued for these stock option exercises are free-trading.

Warrant extension

On November 29, 2018 the Company received approval from the TSX Venture Exchange to amend the expiry date of 1,150,000 common share purchase warrants with an exercise price of \$0.30 issued by the Company in connection with a private placement on December 16, 2016. The expiry date is to be amended from December 16, 2018 to December 16, 2020 with all other terms to remain the same.

**Outstanding Warrants**

The following table reflects warrants outstanding at November 29, 2018. All warrants are exercisable.

<b>Exercise Price</b>	<b>Quantity</b>	<b>Remaining Avg Contractual Life</b>
\$0.30	1,150,000	2.05
\$0.34	2,408,333	1.78
\$0.40	2,005,159	0.64
\$0.50	12,354,493	0.31
<b>\$0.45</b>	<b>17,917,985</b>	<b>0.66</b>

## Outstanding Options

The following table shows the stock options outstanding at November 29, 2018:

Grant Price Range	Options Outstanding			Options Exercisable		
	# of options	weighted avg remaining life	weighted avg exercise price	# of options	weighted avg remaining life	weighted avg exercise price
≤ \$0.25	510,000	2.51	0.18	416,249	2.14	\$0.17
≤ \$0.32	2,950,000	3.63	0.32	1,818,330	3.27	\$0.32
\$0.33 - \$1.25	265,000	1.19	0.97	265,000	1.19	\$0.97
	3,725,000	3.31	0.34	2,499,579	2.86	\$0.36

## Notes and Debentures

The Company has been debt free since March, 2017.

## Profit and Loss

The summary information below is from the Company's unaudited consolidated interim financial statements for the three and nine month periods ended September 30, 2018 and 2017.

	Three months ended September 30		Nine months ended September 30	
	2018	2017	2018	2017
Revenue	60,177	0	60,177	38,903
Cost of Revenue	28,902	28,461	32,095	38,414
<b>Gross Margin</b>	<b>31,275</b>	<b>(28,461)</b>	<b>28,083</b>	<b>489</b>
Total Operating Expenses	906,786	1,249,860	2,908,070	2,426,165
<b>Loss from Operations</b>	<b>875,511</b>	<b>1,278,321</b>	<b>2,879,987</b>	<b>2,425,676</b>
Non-operating Income	760,009	1,403,440	1,783,437	485,572
<b>Loss &amp; Comprehensive Loss (Income)</b>	<b>115,502</b>	<b>(125,119)</b>	<b>1,096,550</b>	<b>1,940,104</b>
<b>Basic and diluted loss per share</b>	0.00	0.00	(0.02)	(0.04)

During 2018, the Company has been ramping up sales and marketing efforts, which has resulted in sales of VMS+ systems in both Q3 and Q4. With the announcement of the next generation VMS+ System (see NR August 8, 2018), which eliminates the need for patients to remain motionless during image acquisition, improves the workflow of the VMS+ through a more intuitive user interface, and has a much smaller footprint with an innovative new tracking sensor technology, many potential customers are now waiting for the launch of the new system.

In Q3 2018 the Company recorded sales of both a VMS+ unit and an upgrade to the 4-Chamber software.

Non-Operating Income (Loss) in 2018 consists almost entirely of the Derivative Liabilities Revaluation Adjustment, which adjusts the value of the Company's outstanding warrant liability to an estimated fair value at September 30, 2018, derived using the Black-Scholes pricing model.

## Operating Expenses

Total operating expenses increased in the first nine months of 2018 from the same period in 2017, by \$482,000.

	Three months ended September 30th		Nine months ended September 30th	
	2018	2017	2018	2017
Research and development	391,762	424,272	1,092,605	832,497
Sales and marketing	212,703	469,633	765,905	632,776
General and administrative	302,321	355,955	1,049,560	960,892
<b>Total Operating Expense</b>	<b>906,786</b>	<b>1,249,860</b>	<b>2,908,070</b>	<b>2,426,165</b>

Of this increase, payroll was up by \$730k, while consulting fees were down significantly as the Company brought R&D and Sales activities in-house with the hiring of staff for both functions. Personnel costs for the nine month periods ending September 30, 2018 and 2017 were as follows:

	September 30, 2018	September 30, 2017	YOY change
Salaries, fees and short-term benefits	\$1,277,069	\$547,348	\$729,721
Share-based compensation	331,640	388,185	(56,545)
<b>Total</b>	<b>\$1,608,709</b>	<b>\$935,533</b>	<b>\$673,176</b>

Employees, directors and consultants are granted stock options as part of their compensation, and the fair value of the options is recognized as Share-based compensation expense as the options vest.

### Sales and Marketing

Sales and Marketing payroll and travel and conference expenses increased by \$185K and \$42K respectively year-over-year as the Company ramped up its sales and marketing efforts in 2018. The Company began hiring its sales team in July, 2017.

Ventripoint exhibited at the 20<sup>th</sup> annual Canadian Society of Echocardiography conference in April, 2018 in Toronto, and at the American Society of Echocardiology's 29<sup>th</sup> Annual Scientific Sessions, June 22-26, in Nashville, TN.

### Research & Development

From 2016 to Q3 2017, R&D activities were outsourced to a consulting company. In Q4 2017, the Company brought the R&D activities in-house and hired 7 new staff, so while R&D consulting expenses to the end of Q3 2018 dropped by \$355k, R&D payroll increased by \$530k from the same period in 2017.

During 2018, the Company has been developing the next generation VMS+ System 3.0 to improve the usability of the VMS technology, reduce the foot print of the product to allow for better integration into hospital workflow, and to reduce the production costs significantly. The development of the new system includes the invention of a small, low-cost, patented device that attaches to any hand-held ultrasound probe and eliminates the need for patients to remain motionless during image acquisition. The VMS+ 3.0 is now undergoing final testing prior to submission to regulatory authorities for approval.

### General & Administration

The Company leased office premises in October, 2017, and as a result rent expense for the first 9 months of 2018 is \$50k higher than in the same period in 2017.

### **Non-Operating Income and Expense**

The components of non-operating income and expense for the three and nine month periods ended September 30, 2018 and 2017 are as follows:

	Quarter ended September 30		Nine months ended September 30	
	2018	2017	2018	2017
<i>Finance costs:</i>				
Interest expense on notes and debentures				(18,981)
Accretion of derivatives issued with debentures				(13,907)
Transaction costs				(405,598)
Bank service charges and other	(1,198)	(974)	(3,349)	(3,998)
<i>Total finance costs</i>	(1,198)	(974)	(3,349)	(442,484)
Gain on shares issued for debt & Other income		18,216		161,982
Foreign currency differences	16,763	15,469	(10,544)	8,956
<b>Non-operating loss before Revaluation Adjustment</b>	<b>15,565</b>	<b>32,711</b>	<b>(13,893)</b>	<b>(271,546)</b>
Derivative Liabilities revaluation adjustment	744,444	1,370,729	1,797,330	757,118
<b>Total non-operating gain (loss)</b>	<b>760,009</b>	<b>1,403,440</b>	<b>1,783,437</b>	<b>485,572</b>

The non-cash Derivative Liabilities revaluation adjustment represents the net decrease (increase) in the fair market value of the Company's outstanding warrants, calculated at the time of each warrant exercise, convertible debenture retirement or conversion transaction, as well as at the end of the period. The fair value of the warrants depends on a number of factors, including; the Company's stock price at the date of revaluation, exercise price or conversion price, risk-free interest rate, volatility of the Company's stock price, expected life of the derivative, the estimated number of warrants that will actually be exercised in future periods and the expected annual dividend rate for future periods.

Over the 9 month period to September 30, 2018, the Derivative Liability balance has fallen from \$2.2M to \$134,364, due to the expiry and exercise of 1.3M and 2.2M warrants, respectively, the reduced weighted average remaining life of the outstanding warrants to 0.44 years from 1.15 years, and a rise in the risk free interest rate of over 0.50%. In addition, the past year has seen a reduction in the Company's share price volatility.

New warrants issued in the September 2018 Unit Private Placement (see **Capital Transaction – 2018 Year to Date** above), are not considered derivatives and therefore are not accounted for as liabilities. Their fair value on issuance is recorded in Contributed Surplus and is not revalued at each balance sheet date.

## Liquidity

The following summary shows the primary sources and uses of cash in the first nine months of 2018.

	<b>YTD 2018</b>
<b>Cash balance - December 31, 2018</b>	<b>\$1,358,923</b>
<i>Sources of cash:</i>	
Unit Private Placement	1,011,500
Warrant and Option exercise proceeds	778,500
Sales collections	1,437
HST sales tax refund	99,809
	<u>1,891,246</u>
<i>Uses of cash:</i>	
Cash operating expenses	(1,157,600)
Inventory purchases	(56,835)
Equipment purchases	(25,772)
	<u>(1,240,207)</u>
<b>Cash balance –September 30, 2018</b>	<b><u>\$651,039</u></b>

On September 4<sup>th</sup> and September 13<sup>th</sup>, 2018 the Company closed two tranches of a non-brokered private placement (the “Private Placement”) for total gross cash proceeds of \$1,011,500, with the sale of 4,816,666 units (“Units”) at \$0.21 per Unit (see **Capital Transactions – 2018 Year to Date** above).

A retail sales tax refund from the Government of Canada of \$99,809 was received in March, 2018 and 2,206,667 Warrants and 450,000 options were exercised in the first half of 2018, for total proceeds of \$662,000 and \$116,500, respectively.

During 2018, the level of inventory has increased in anticipation of sales in Q4 and Q1 2019. Amounts receivable at September 30, 2018 include \$62,559 in receivable from sales, and \$60,750 in refundable sales tax due in February, 2019.

## Contractual Commitments

The Company has the following contractual cash obligations as of November 29, 2018:

	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021- 2027</b>	<b>Total</b>
Premises lease	\$3,772	\$45,575	\$46,799	\$84,727	\$180,873
University of Washington Technology License					
Minimum Annual Royalty	-	6,439	6,439	45,070	57,948
<b>Total contractual commitments for the</b>	<b>\$3,772</b>	<b>\$52,014</b>	<b>\$53,238</b>	<b>\$129,797</b>	<b>\$238,821</b>

On October 1, 2017 the Company entered into a 5 year lease for office premises at 2 Sheppard Avenue East, Suite 605, Toronto, Ontario. The cash obligations shown above are the annual Base Rent due over the term of the lease.

The annual Royalty due to the University of Washington under the Technology License Agreement is the higher of 1.5% of gross sales or the Minimum Annual Royalty of US\$5,000.

## **RISKS AND UNCERTAINTIES**

### Financial

The Company's success in raising new operating capital has enabled it to finalize its VMS+ development and implement initial commercialization strategies. The Company may 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 the expansion and enhancements of product applications 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.

### Regulatory

On May 15, 2018 the Company announced that it had received market clearance from the US FDA to sell its VMS+ machine with the 4-chamber heart analysis system in the US. The intended use is for the analysis of ejection fraction (function) and volumes of any chamber of the heart, where they are warranted or desired. This is an expansion of the VMS heart analysis product to include right atrium, left atrium and left ventricle chambers of the heart. This expansion allows for the determination of volume and function for all four chambers of the heart using conventional 2D ultrasound, which could only be provided by MRI until now.

The VMS+ and the 4C system received European CE Mark on December 15, 2017.

In March, 2017, the Company received a license from Health Canada for the VMS+ and the 4C heart analysis system. The VMS was already licensed in Canada for use for the right ventricle (RV).

### 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.

## **CRITICAL ACCOUNTING ESTIMATES**

The Company's audited annual consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards. Certain accounting policies require that management make appropriate decisions with respect to the formulation of estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. The Company's primary critical accounting estimates relate to the valuation of its issued common stock warrants and stock options. The Company applies the fair value method for valuing stock option grants and the issuances of warrants. The fair value is estimated on the date of grant or issue, and the warrants issued prior to September 2018, which are treated as derivative liabilities, are revalued at each balance sheet date using the Black-Scholes option pricing model or specialized Binomial model required to reflect the impact of the acceleration of the expiry date under certain circumstances. The fair value of the Warrants issued in September, 2018 is recorded as Contributed Surplus. In order to calculate the fair value of options granted and warrants

at issuance and for period end revaluation, the following information is required: stock price at date of grant, issue or revaluation, exercise price of option or warrant, and vesting periods. In addition, are the following where management is required to make assumptions: risk-free interest rate, volatility of the Company's stock price, expected life of the option or warrant, the estimated number of options or warrants that will actually be exercised in future periods and the expected annual dividend rate for future periods. See Notes 7 and 8 of the September 30, 2018 unaudited condensed consolidated financial statements for weighted average assumptions used to determine the fair value of the Company's options and warrants. Other accounting judgements include the designation of the Canadian dollar as the Company's functional currency.

## **ADDITIONAL INFORMATION**

Additional information relating to the Company can also be found on SEDAR at [www.sedar.com](http://www.sedar.com).