



**VENTRIPOINT DIAGNOSTICS LTD.**

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

**For the nine months ended September 30, 2017**

**November 29, 2017**

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## **MANAGEMENT’S DISCUSSION AND ANALYSIS, NOVEMBER 29, 2017**

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, 2017. 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, 2017.

### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

In the interest of providing current and potential investors in Diagnostics 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.

## **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 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 4D imaging equipment (real-time 3D imaging is now considered to be 4D with time as the fourth dimension). The Company's technology platform is applicable to all heart diseases. The VMS system is based upon patented technology that Ventripoint has licensed on an exclusive basis from the University of Washington. The VMS has US-FDA marketing clearance, Health Canada license and European CE Mark for all patients, where right heart information is warranted or desired. In addition, the Company announced the granting of a license from Health Canada for all 4 chambers of the heart on March 2, 2017. The Company is in the early stages of commercialization. As further described below, current efforts are focused on:

- Marketing the 4-chamber VMS in Canada and other jurisdictions where “home-country approval” will facilitate product registration;
- Obtaining regulatory approvals for the 4-chamber VMS in other jurisdictions including the USA, Europe and 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;
- Establishing a partnership to manufacture, market and distribute existing and future VMS products in China. The Company will retain the rights to market existing and any new devices outside of China; and
- Completing its VMS-4DE application to be used with 4D scanning equipment for the developed world where 4D systems are available but underused for volumetric measurements due to technical issues, which can likely be overcome by the KBR approach.

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 4D echocardiography 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 other types of heart disease where the RV information is warranted or desired. The VMS product remains the only approved way to generate substantially equivalent results to the gold-standard MRI for right ventricular volumes using 2D echocardiography. The Company has recently received approval in Canada for all a major expansion of the VMS product to be applied to 4 chambers of the heart. The Company is building a sales and distribution team to capitalize on the recent product expansion. The Company is also looking to expand the product offering to include an integrated 2D system, which would do routine echocardiography as well as the 4C-VMS on a single device. The Company recently invented a new way to track ultrasound probes and has built a prototype device to demonstrate its ability to speed up image capture and reduce the artefacts due to patient movement during scanning (see NR on November 27, 2017). The development of the 4C-VMS for semi-automated analysis of 4D is being considered, but requires a significant improvement of the 4D ultrasound images, which is beyond the scope of the Company at this time. 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 Structure and Strategy**

Late in 2015, the Company refocused its efforts on developing the VMS to analyze all 4 chambers of the heart in response to market research on the needs of the cardiology community. In the developed countries, cardiologists were asking to use 4D ultrasound scanning, which was not routinely used due to the difficulty in obtaining and analyzing the images. The 4D images continue to get better as the technology improves but it is estimated that 20-25% of patients will always need to be scanned using 2D ultrasound due to poor windows (body size and shape) for ultrasound. In the emerging world, 2D ultrasound is still dominant, but cardiologists would prefer one device with

both VMS and routine echocardiography functions. Hence, the Company developed a strategy to develop an integrated 2D ultrasound device in partnership with existing manufacturers and to expand both the 2D applications to all 4 chambers of the heart. The integrated VMS will take approximately a year to be developed and 6 months to be approved once a partner has been secured, so the Company has completed the development of a new model called the 2D-VMS-PLUS machine and this has been approved in Canada.

The overall strategy is to have a suite of products available to allow customers with existing 2D ultrasound machines to purchase the VMS-PLUS 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 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 also develop the VMS analytical software package for 4D ultrasound as the 3D spatial data is already embedded in the 4D scans and so no additional hardware will be required. The 4D ultrasound machines currently only provide readable images in about 50% of patients and so are clinically not used for global heart measurements. The Company still believes that the KBR approach is the best approach to build a semi-automated analysis package for 4D scans. 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 4D would need to buy both products to effectively and efficiently examine all their patients.

The Company has appointed experts in ultrasound and biomedical commercialization. In November, 2015, the Company appointed Dave Willis to the Board of Directors (see NR November 4, 2015). 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 (see NR February 15, 2016) 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 company 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, Brian Leck was appointed as Vice-President of Direct Worldwide Sales. Brian has extensive experience in the healthcare industry. He has worked in a variety of companies with a breadth of vibrant products focused on hospital care areas. In his most recent position, he was the

Vice President/General Manager for Global Direct Sales for Fujifilm-Sonosite, Inc, which sells portable ultrasound devices into office and hospital care areas. From 2012 through 2014, he ran Direct and Distributor sales for North and South America, with an emphasis on growth in specific hospital care areas. During that tenure, he was instrumental in creating a wholly owned subsidiary in Brazil. The organization included sales, marketing, finance, regulatory and a repair facility all within the headquarters in Sao Paulo. From 2015 through 2017, he was responsible for Global Direct Sales, managing sales and marketing in the USA, Canada, Australia/New Zealand, Korea and Western Europe. He was also responsible for a shared services facility in Amsterdam that included marketing, service and repair, finance and credit, human relations, sales administration and local shipments.

Also 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. 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.

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 (see NR February 15, 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 future development projects such as the VMS-4DE project.

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 (See NR January 21, 2016). 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-PLUS to be manufactured more easily, while reducing the foot print and weight of the machine. They also made the VMS-PLUS more mobile and upgraded the computer hardware to current standards and to work with the newer 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-PLUS hardware has been finalized and regulatory approval received in Canada. The VMS-PLUS will require a new ISO60601 certification so it has been sent to an international standards laboratory for final testing to this standard.

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-PLUS heart analysis units in China. The first machine was constructed in 4Q16 and an additional 3 machines have been fabricated in 1Q17. 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 C-FDA for approval of the VMS-PLUS 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. In discussions with leading cardiologists, they have expressed the need for a volumetric analysis package for all 4-heart chambers. A prototype application for left ventricle analysis (LV) was developed, which included the creation of a LV database from the existing inventory of heart images, which the Company has amassed over several years. This application has been used for clinical research by a major European heart centre, which reports that it is more accurate than existing analysis techniques, especially when the LV has been deformed in the setting of RV dysfunction. With the clearance in the United States of the RV database for all patients where RV analysis is desired or warranted (see NR, May 26, 2015), the Company has been encouraged to make commercially available databases for the other 3 chambers of the heart. While RV volume measurements are valuable in congenital heart diseases and pulmonary hypertension, there is an emerging demand for accurate volumetric measurements of the LA and RA to inform the selection of the appropriate monitoring and treatment of patients who require pacemakers, those at risk for atrial fibrillation (AF), as well as those with acute heart attacks (myocardial infarctions). All the VMS analytical products; 2DE, 4DE or CMR (for use with MRI images) can use the same catalogues for the different heart chambers to generate volumetric measurements. Initially thought to be years away, Ventripoint has completed the development for the 4-chamber feature to be used with 2D ultrasound equipment and obtain regulatory clearance in Canada and is available for commercial release in Canada, once ISO60601 certification is received.

The Company has focused on upgrading the VMS machine to a new model, the VMS-PLUS™. It's 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 has heard from its regulatory advisors that the VMS-PLUS does not need to undergo clinical testing prior to final submission for regulatory approvals and commercial production, but does need to be re-certified to the ISO 606601 standard. The Company has had an independent laboratory do the testing of the VMS-PLUS and believes it has passed the testing and is waiting the final report. Accordingly, the Company will be submitting to have the VMS-PLUS included in its product offering for the USA and Europe once IOS60601 certification is received. The development and manufacturing facility in Toronto passed an ISO audit in June 2016 (see NR June 24, 2016) and more recently on May 26, 2017, as well as a surprise audit in August, 2017 (it is routine to have surprise audits), and is ready to manufacture this new model in Canada for worldwide use.

## **Sales and Marketing**

Now that the 4-chamber system has been approved in Canada and the VMS-PLUS has been also approved in Canada, the Company has launched a sales effort for the new 4C-2DE-VMS-PLUS product. 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 three settings where the VMS is regarded as critical to providing the best cardiac diagnosis and monitoring. This process has been completed and a direct sales effort has begun in Canada. These sales calls will further validate the sales materials and are expected to generate sales.

The marketing team has been prioritizing markets by size and ease of entry from a regulatory perspective. Asia and regions in the Middle East are the current foci. Presentations and discussions have been held in both regions. Interest in the Ventripoint products is strong from Iran, Singapore, Thailand, U.A.E. and Saudi Arabia. Regional distributors are verifying the local pathway to regulatory approval and market size. While in some cases they can initiate local product registration based on Health Canada approval, in other regions a longer process is required and it may be best to wait until CE Mark or FDA approval for the 4-chamber VMS has been secured. The Company expects to have clear channel partners identified for multiple countries within these two regions by the beginning of December.

Upon approval of the CE Mark, we will advance the European markets and other regions, which require CE Mark. The Company is aiming to launch distributor and direct sales discussions in early December at the EuroEcho Conference in Lisbon, which is attended by most distributors. This is an excellent platform for phase two of our channel expansion.

The third phase will be the United States markets. We are expecting marketing clearance for the 4-Chamber VMS sometime in early 2018. At that time, we will implement our launch strategy regarding representatives, locations and defining regional initiatives.

The Company has also been interviewing leading cardiologists to identify specific cardiac conditions where clinical studies would verify the need for the VMS. These experts have identified, uncontrolled hypertension (30 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.

Ventripoint has identified enthusiastic cardiologists in Canada, Europe and the Middle East, who wish to conduct clinical trials to verify the importance of chamber volumes in all these clinical settings and is working with them to develop protocols and begin the studies.

A recent focus has been on the Middle East and North Africa (MENA) region, where heart disease is particularly prevalent. For example; cardiovascular disease is responsible for one in five deaths in the United Arab Emirates (UAE) and one in four adults in Saudi Arabia are likely to have a heart attack within the next 10 years. The UAE has 70 public and private hospitals and 150 medical centres and clinics and is opening a new hospital every month. Saudi Arabia has approximately 600 hospitals and 2,282 clinical centres and is expanding its healthcare system.

The Company hired a representative for the region who attended the CSI Dubai 2017 cardiac conference in Dubai in April. He met with 70 cardiologists from the region and made calls at local

hospitals to verify their readiness. In August, 2017, a second trip the region by the CEO and the consultant continued the effort to establish a presence. The Company met with a regulatory consultant for the region, who confirmed that the Health Canada approval would be sufficient to register the product in the UAE. The Company also met with potential distributors, as well as administrators and chief cardiologists of the leading cardiac hospitals in Dubai and Abu Dhabi. The VMS-PLUS offering was well received and viewed as an innovative product to improve cardiac care. Some new areas of application were identified and discussions are ongoing with potential clinical study sites. On November 15, 2017 the Company announced it had signed a memorandum of understanding (MOU) establishing 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 will initially focus on making hospitals, doctors and officials aware of the unique features of the VMS-PLUS through research, conferences and opportunities designed to demonstrate its population health applications. Simultaneously, regulatory approvals for full clinical use will be obtained so sales efforts can begin in the new year.

Hisham Al Gurg, CEO of the SEED Group commented "We are very excited about the potential of this strategic partnership with Ventripoint and are very proud to introduce their innovative healthcare solution into the region. At SEED Group, we specialize in assisting unique firms, like Ventripoint, with establishing a presence in the United Arab Emirates as they expand beyond their home markets. UAE is fast building its reputation as icon for innovation and creativity attracting companies like Ventripoint, which is a natural fit into the country's national innovation and healthcare hub strategy.

Over the past 16 years, the SEED Group has formed strategic alliances with leading global companies representing diverse regions and industries. These companies have propelled their business interests and goals in the MENA region through the support and strong base of regional connections of the SEED Group. The Group's goal is to create mutually beneficial partnerships with multinational organizations and to accelerate their sustainable market entry and presence within the MENA region. The SEED Group has been a key point in the success of all its partners in the region helping them reach their target customers and accelerate their businesses. The Private Office was established by Sheikh Saeed bin Ahmed Al Maktoum to directly invest in or assist potential business opportunities in the region, which meet The Private Office's criteria.

World Expo 2020 will be held in Dubai and is expected to attract 33 million visitors. By 2020 UAE plans to make Dubai a major healthcare hub by showcasing the latest medical updates and innovations, treatment modes and technologies including Ventripoint and growing its market to be worth around USD \$12B by the time of Expo 2020.

Michael Slage has been appointed as a consultant to the Company to be the primary liaison with the SEED group. Mr. Slage was formerly an International Relations Specialist for NASA and has been instrumental in negotiating contracts and investment worth over \$350 million dollars for companies such as Boeing, GSK, Johnson & Johnson and Bayer.

The region is especially interesting as a major imaging company recently signed a memorandum of understanding with the Ministry of Health for the U.A.E., whereby it will equip and service radiology departments in 11 hospitals in exchange for per patient service fees. This is the model the Company would like to deploy in the region and to our knowledge it is the first agreement using this model for imaging products.

In Q2 2017, 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, 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 hired a new application specialist who will accompany sales staff on sales calls and train new users. She has undergone in-depth training in Toronto and will continue to interface with clinical centres as well as being available for sales calls.

An additional opportunity is emerging with the proliferation of 4D ultrasound equipment in the developed countries. The VMS technology can provide analysis of 4D ultrasound images of the heart with the same accuracy as MRI. The development team has developed a prototype analytical software package to be used with 4D echocardiograms (VMS-4DE™) and one to be used with MRI images (VMS-CMR™). These have undergone initial clinical evaluation for accuracy and have been shown to be accurate when compared to the method of disks analysis of MRI images, which is the gold-standard technique. A group led by Dr. Kai Laser at the Center for Congenital Heart Defects, Bad Oeynhausen, Germany, has published the results of a clinical study that demonstrated the robust application of the VMS heart analysis technology using cardiac MRI (CMR) and 4D ultrasound imaging in a wide range of cardiac conditions ([“Knowledge-based reconstruction of right ventricular volumes using real-time three-dimensional echocardiographic as well as cardiac magnetic resonance images: comparison with a cardiac magnetic resonance standard.”](#) Laser KT, Horst JP, Barth P, Kelter-Klöpping A, Haas NA, Burchert W, Kececioglu D, Körperich H. J Am Soc Echocardiogr. 27(10):1087-97, 2014). An accurate 4D analysis approach is needed as the current 4D ultrasound analysis approaches are widely accepted as inaccurate in calculating volumes except for normal LV volumes, which can easily be calculated from 2DE scans.

The current use of 4DE 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 4DE concerning coverage, image quality and lack of feasibility when looking at volumetric functional assessments and allow its use for routine clinical assessments of the heart. Indeed, the German study confirms the accuracy and precision using selected, good-quality, readable 4D studies. The VMS-4DE product needs additional work on the user interface to increase the ease of use and the hardware for the 4D scans needs to evolve to increase the overall feasibility of obtaining readable images, prior to embarking on commercialization.

The Company will be seeking government assistance in Canada to offset the costs of the VMS-4DE development. The Company is also exploring the merits of using KBR-assisted automated border detection with research groups that specialize in creating algorithms for border detection. Should one of these groups determine they can produce a better algorithm, the Company would enter into an agreement to seek additional research funding for the project. The Company is also seeking partners to assist in commercializing the VMS-4DE product. Ventripoint will announce any agreements if and when they are completed.

## **Clinical Evaluations and Demonstrations of Meritorious Use**

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 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.

## **Independent Clinical Studies**

On August 21, 2017 the Company announced that the cardiology group at Royal Free Hospital in London, UK has 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-PLUS 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-PLUS was used.

**Re-Admission Study:** The Company is discussing with major cardiac centres in Canada and the US the initiation of clinical studies in left heart failure to determine if analysis of the RV using VMS during initial and subsequent patient admissions to a hospital would reduce the re-admission rate within 30 days, which is currently 21% in the US. It is estimated that over 1 million re-admissions happen annually in the US. In 2004 alone, the cost to Medicare for heart failure re-admissions totalled \$17.4 billion ([http://www.heart.org/idc/groups/heart-public/@wcm/@private/@hcm/@gwtg/documents/downloadable/ucm\\_432944.pdf](http://www.heart.org/idc/groups/heart-public/@wcm/@private/@hcm/@gwtg/documents/downloadable/ucm_432944.pdf)). In the US, Medicare and Medicaid withhold a percentage of billings from hospitals with higher than acceptable re-admission rates. The withholding was 1% in fiscal year (FY) 2013, 2% in FY2014 and 3% in FY2015. Two thirds of hospitals, or 2,213 hospitals, were penalized in FY2013, which ended September 30, 2013, for a total of \$280 - \$320 million at the 1% level (<http://www.advisory.com/Daily-Briefing/2013/08/05/CMS-2225-hospitals-will-pay-readmissions-penalties-next-year>). It has been reported that 2,600 hospitals were penalized in FY2014 and 2,592 hospitals will receive lower payments for every Medicare patient that stays in the hospital for FY2015. The total penalty for FY2015 at the 3% level in the fourth year of the program was estimated to be \$420 million (<http://www.khn.org/news/half-of-nations-hospitals-fail-again-to-escape-medicare-readmission-penalties/>).

While the penalties for high re-admission rates are significant to hospitals, a larger issue is bed utilization. The average cardiac admission lasts for 6.5 days and generates about 50% of the revenue per bed-day than for average admissions. Thus, the cardiac re-admissions significantly affect the hospitals’ average revenues per bed-day. Some procedures, where patients are hospitalized for a few days, generate 5 times greater revenue per bed-day than a routine cardiac admission. Accordingly, hospitals would benefit in two ways by acquiring a VMS; lower penalties and higher revenues from bed utilization. Patients in left heart failure do not routinely undergo functional RV analysis and yet research studies using MRI have shown that functional RV analysis is prognostic. The recent imaging guideline has recommended functional right heart assessments for all patients.

On November 11, 2014, the Company announced that the Montefiore-Einstein Center for Heart and Vascular Care in the Bronx, New York City, had begun a clinical study.

Dr. Mario Garcia and Dr. Ileana Piña are leading the study. Dr. Piña is a nationally renowned cardiologist known for her work in heart failure and development of multidisciplinary clinical interventions to improve patient rehabilitation outcomes. Dr. Piña serves as advisor/consultant to the FDA's Center for Devices and Radiological Health and their section of Epidemiology. She is also a consultant to Novartis Pharmaceuticals and GE HealthCare. She is the author/co-author of over 100 publications in print, and a world-renowned speaker on heart failure management. Dr. Piña was on the writing committee of the new American Heart Association Guidelines for the Prevention of Heart Disease. Mario J. Garcia, MD, is Chief of the Division of Cardiology and Co-Director of the Montefiore-Einstein Center for Heart and Vascular Care. Dr. Garcia is an internationally known leader in the development and clinical advancement of cardiac diagnostic technology, including cardiac CT, echocardiography and cardiac magnetic resonance imaging. Dr. Garcia is board-certified in cardiovascular medicine, internal medicine and echocardiography.

Montefiore Medical Center is a 1,418-bed general medical and surgical facility in the Bronx, New York. It ranked among the top hospitals nationally in Cardiology and Heart Surgery, in *U.S. News & World Report's* "America's Best Hospitals" 2014-2015 survey. Through its enduring partnership with Albert Einstein College of Medicine, it combines clinical care with research to deliver the most current treatments available.

The pilot trial will evaluate the ability of VMS analysis to identify the patients who will return within 30 days and determine the degree RV function is impaired in this group. If a positive correlation can be established between RV function and re-admission to hospital, a second study looking at treatment modifications to prevent or delay re-admissions will be initiated. This study has the potential to revolutionize how cardiac patients are assessed and save the healthcare system billions of dollars by reducing re-admission rates as more appropriate therapy is applied to those patients in left-heart failure with right-heart involvement.

The Company has done an analysis of the effect of a 5% reduction in re-admission rate and determined the average hospital would benefit with \$1.3 million in new or recovered revenue from better bed and MRI usage, as well as recovery of penalties and re-imbursements for the VMS procedures themselves. The study will also look at 90 day re-admission rates to determine additional benefits from functional RV analysis.

To date, 155 patients have been enrolled in the Montefiore study. An interim analysis failed to show a significant correlation between 30-day re-admission and RV size and function. More patients will be required to definitively determine the correlation (or lack thereof). In light of the current uncertainty in the healthcare environment in the USA, the study has been halted pending the resolution of the changes in the Affordable Care Act that may eliminate the penalties for cardiac re-admissions.

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 recent 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-PLUS.

There are 1.7M new cancer patients/year in the USA as people now have a 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 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.

2. Cardiac resynchronization therapy (CRT) or the implantation of pacemakers continues to be standard practice for patients with arrhythmias. There are 600,000 pacemaker implantation a year worldwide at a cost of \$18-\$60B or USD\$30,000-\$100,000 per patient. While 1/3 of the time this procedure improves heart function, 2/3 the time is does nothing or causes additional stress on the heart. More and more cardiologists are asking for accurate volumes and ejection fractions for RA and LA to determine who should receive a pacemaker. The assessment using 4-C-2DE-VMS-PLUS has the ability to provide accurate information in a rapid and easy manner and has the potential to save healthcare system significant costs due to unwarranted pacemaker implantations.
3. High blood pressure of hypertension continues to be a major risk factor for heart attacks and other cardiac conditions. A recent 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 the 64 million U.S. adults with hypertension did not have this condition under control in 2014. 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-PLUS using conventional 2D ultrasound. Every cardiologist has access to a 2D ultrasound service or machine and so could begin this cost-reduction program immediately. Once again the key is accurate, reliable and rapid assessment of LA volume.

The Company will be focusing on the above three applications and approaching leading cardiologists who have published in these areas to further advance the state-of-the-art towards measuring heart chamber volumes routinely.

## **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 payers. 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. Ventripoint is now installed at leading cardiac sites in the US, Europe, Canada and China. To build VMS awareness in the Company's targeted medical professional market segments, these VMS deployments were 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.

In July, 2013, when the Company exhibited at the 24<sup>th</sup> Scientific Sessions of the American Society of Echocardiology in Minneapolis, Minnesota three scientific papers were presented by three groups of researchers discussing the clinical use of the VMS.

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".

In July 2013, 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, August 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”.

On April 2, 2014, the Company reported on the completion of two clinical studies, one in PAH and one in congenital heart disease. Both studies verify the utility of the VMS in monitoring patients after treatment to determine if the therapy has been effective.

Dr. Johannes Schwaiger of the Department of Cardiology at Royal Free Hospital in London will be lecturing 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*”.

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...*”

On November 5, 2014, the Company reported that the 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*”.

In April, 2015, a paper titled “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. The imaging guidelines, published by the American Society of Echocardiography (ASE) in the Journal of the ASE, are written by experts in the field of echocardiography and cardiology, and provide a recommended standard of care.

This VMS validation and awareness campaign was intended to engage the support and endorsement of opinion leaders and to position VMS for broad acceptance by clinicians in Canada, Europe and in the US.

In June 2016, the Company exhibited at the 27<sup>th</sup> Scientific Sessions of the American Society of Echocardiography in Seattle. There continues to be more scientific presentations on RV each year at this major congress. In 2016, there were also papers on the evaluation of the LA and RV and the limitations of existing techniques.

In May 2017, a Company representative attended a regional cardiology conference in the Middle East and met with 40 major cardiology groups, who expressed a desire to acquire the VMS-PLUS and requested an on-site demonstration at their hospitals. The Company is planning a marketing trip, once Ramadan is over, and is in the process of hiring and training a new application specialist to accompany the marketing team on the trip. The Company has identified a regulatory representative to facilitate registration of the VMS-PLUS in the Gulf States region and is currently interviewing potential distributors to establish a team in the region for ongoing training, maintenance and support.

From November, 2013 until March, 2014, the Company was focused solely on obtaining FDA clearance and minimal efforts were put towards sales and marketing. With the FDA clearance received on March 10, 2014, the Company re-initiated contact with the cardiology community in the United States, Europe and Canada to promote clinical use and sales. The Company became focused on initial marketing strategies, which included:

- Exhibiting at the annual meeting of the American Society for Echocardiography in June, 2014 in Portland, Oregon and attending other conferences to meet with cardiologists.
- Contacting American cardiologists who have previously indicated an interest in functional heart analysis,
- Signing up distributors in the rest of the world,
- Furthering discussions with select leading ultrasound manufacturers for collaborations on technology integration,
- Advancing hospital-sponsored clinical studies into new applications for the VMS, and

- Re-evaluating marketplace acceptance of a pay-per-use structure in patients with left heart failure, while maintaining the current capital purchase approach in Pulmonary Hypertension and Congenital Heart Disease applications.

The Company exhibited at the EuroEcho Conference in Vienna from December 3-6, 2014. More than 3,500 participants who focus on echocardiology attended EuroEcho-Imaging 2014, which is the official annual meeting of the European Association of Cardiovascular Imaging, a registered branch of the European Society of Cardiology.

The Company attended the American College of Cardiology Scientific Sessions, March 14-16<sup>th</sup>, 2015, in San Diego, CA. We met with key potential customers who have asked for our time to engage in further discussions with regard to our product. The event was an excellent opportunity to communicate directly with those customers currently interested in purchasing a VMS system.

The Company exhibited at American Society of Echocardiography Scientific Session (ASE 2015) held 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.

On March 30, 2015, the Company announced the appointment of PYP Enterprises LLC (PYP) to be the exclusive distributor to the US military hospitals including the VA hospitals. PYP Enterprises LLC is a preferred provider of services to the Department of Defense and is designated as a service-disabled, veteran-owned, small business (SDVOSB) by the US Department of Defense. The US Department of Defense is required to purchase products worth 6% of its budget from SDVOSBs and the VA is required to spend 3% of its annual budget on products from SDVOSBs. This agreement has lapsed due to the need to expand the VMS product to 4 chambers and it is unclear if it will be re-instated with this partner.

On September 2, 2014, the Company announced that it had signed a distribution agreement with Shandong Realcan Pharmaceuticals Co. Ltd (“Realcan”, Shenzhen Exchange:002589). The Company was informed in March, 2015 by Realcan that they were not ready to move forward with the distribution agreement and investment. The agreement was terminated and all rights returned to the Company.

## **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 (see NR November 10, 2015) 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-PLUS 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 machine have been fabricated in 1Q17. 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. YuTian has applied to the C-FDA for approval of the VMS-PLUS with RV analysis software and expects to have marketing approval in 2017. 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.

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.

## **Regulatory**

**Canada and Europe** As previously reported, the Company has received Health Canada approval and has also 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. 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.

In December, 2014, the Company successfully completed an ISO 13485 re-certification audit, which is carried out every three years.

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

**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 U.S. Food and Drug Administration (FDA) on January 8, 2015. This initial Establishment Inspection following 510(k) clearance of the Ventripoint Medical System in March, 2014, was started on December 29, 2014 at the Company's Bellevue, Washington location. It 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.

## FINANCIAL HIGHLIGHTS

These Financial Highlights should be read in conjunction with Ventripoint Diagnostics Ltd.'s condensed consolidated interim financial statements for the three and nine month periods ended September 30, 2017 and the corresponding notes thereto.

Unless otherwise specified, all financial data herein is presented in Canadian dollars.

### Capital Transactions

The fully diluted share capital of the Company as of November 29, 2017 is as follows:

	Issued and Outstanding				Fully Diluted
	Common Shares	Convertible Debentures	Warrants	Options	
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)	-
DSUs exercised	150,000				150,000
Warrants cancelled/expired			(4,104,195)		(4,104,195)
Warrants exercised - 2008 - 2012	651,056		(651,056)		-
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	4,086,665		4,738,331
<b>2017 activity:</b>					
Warrants exercised - 2017	5,904,130		(5,904,130)		-
Warrants expired			(300,000)		(300,000)
Stock options granted, net of expiries, cancellations				2,488,000	2,488,000
Stock options exercised - 2017	425,000			(425,000)	-
Conversion of debentures - 2017	766,666	(766,666)			-
Cash repayment of convertible debentures - 2017		(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	10,779,493		10,779,493		21,558,986
<b>Issued and outstanding, November 29, 2017</b>	<b>51,588,507</b>	<b>-</b>	<b>19,321,765</b>	<b>3,169,400</b>	<b>74,079,672</b>

As of November 29, 2017, officers and directors held 3.4% of the outstanding common shares of the Company (6.2% on a fully diluted basis).

## **Equity and Debt Transactions - 2017 year to date**

### *a. Unit Private Placement*

On March 24, 2017 the Company announced that it had closed a non-brokered private placement of 10,496,938 units (“Units”) at \$0.32 per Unit for total gross proceeds of \$3,359,020. Existing shareholders subscribed for \$1.9M and new shareholders subscribed for \$1.4M of the Private Placement. Each Unit consists of one common share of Ventripoint and one common share warrant (“Warrant”), with each Warrant entitling the holder thereof to acquire one common share at a price of \$0.50 per common share for a period of two years after the issuance of the Warrant. Dr. George Adams, the CEO and a Director of the Company, subscribed for 312,000 Units.

The Company paid cash finder's fees of \$188,030 and issued an aggregate of 282,555 common shares and 282,555 non-transferable common share purchase warrants (the "Finder's Warrants") to finders in connection with the placement. Each Finder's Warrant is exercisable into one common share at a price of \$0.50 per common share for a period of two years from the date of issuance.

### *b. Shares for Debt Unit Private Placement*

On March 21, 2017, as part of the private placement, the Company closed a shares-for-debt transaction (the “Shares for Debt”) with holders of debentures (the “Debentures”). The Company issued a total of 1,575,000 of the Units in payment of \$504,000 of debenture amounts due. Dr. George Adams, the CEO and a Director of the Company, received 312,500 Units pursuant to the Shares for Debt.

### *c. Debenture Conversions and Repayments*

During March, 2017 holders of \$115,000 in convertible debentures converted the debentures into 766,667 common shares, and the Company repaid in cash the remaining \$109,000 in outstanding Debentures, leaving the Company debt free by March 31, 2017.

### *d. Warrant and Option Exercises*

Year-to-date, the Company has issued 5,904,130 common shares due to the exercise of warrants at exercise prices between \$0.15 and \$0.40, for total proceeds received of \$1,250,236. In addition, 425,000 shares have been issued as a result of the exercise of stock options for proceeds of \$68,250. The common shares issued due to these warrant and stock option exercises are free-trading.

### *e. Stock Option Grants*

On January 6, 2017 the Company announced that FronTier Consulting Ltd. (‘FronTier’) has been retained for 12 months to provide IR services for a fee of \$6,000 payable on a quarterly basis, and to provide additional marketing consulting services for \$60,000. Under the terms of the agreement the Company issued 200,000 stock options to FronTier at an exercise price of \$0.15, vesting in equal quarterly installments over 12 months and expiring two years from the date of grant. To date, FronTier has exercised 100,000 stock options for proceeds of \$15,000.

On May 2, 2017 the Board of Directors granted 445,000 common stock options to six consultants in payment for their services, with an exercise of \$0.32 per share, a two year term and vesting quarterly over one year. In addition, the Board granted 100,000 stock options to the CFO of the Company, with an exercise price of \$0.32 and a maturity date of May 2, 2022, which vested immediately.

On June 22, 2017 the Board of Directors granted 50,000 options to a consultant of the Company.

Effective July 1, 2017 the as a condition of employment, the Company granted to new Vice-Presidents, Brian Leck and Mehran Mehrtaash, 250,000 option grants each, at an exercise price of \$0.32 for term of 5 years, vesting quarterly over two years.

On July 20, 2017 the Company announced that the Board of Directors of the Company has granted the new Vice President, Development and Operations, Desmond Hirson, 250,000 option at an exercise price of \$0.32 for term of 5 years and vesting quarterly over two years, effective on August 1, 2017.

On August 16, 2017 the Company announced that the Board of Directors has granted a total of 1,250,000 common share stock options to the CEO, CFO, and three Vice-Presidents of the Company. George Adams, CEO, received 300,000 new options and both the CEO and the CFO received 100,000 options each in replacement of options which were cancelled on July 1, 2017. All options are exercisable at \$0.32 per share until the fifth anniversary date of the grant. The new Vice-Presidents received 250,000 options each, vesting quarterly over 3 years.

The Company also announced that it has granted a total of 300,000 Deferred Share Units (DSUs) to four independent Directors in recognition of their past and future services to the Company. Under the terms of the Company's Deferred Share Unit Plan, holders of DSUs may redeem each DSU for one share of common stock upon the termination of their services to the Company at no cost to the holder.

## Outstanding Warrants

The following table reflects warrants outstanding at November 29, 2017. All warrants are exercisable.

<b>Exercise Price</b>	<b>Quantity</b>	<b>Remaining Avg Contractual Life</b>
\$0.15	165,000	0.90
\$0.30	3,356,667	0.99
\$0.40	3,445,604	1.21
\$0.50	12,354,493	1.31
<b>\$0.44</b>	<b>19,321,764</b>	<b>1.23</b>

## Outstanding Options

The following table shows the stock options outstanding at November 29, 2017:

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
< \$0.60	2,780,400	0.72	\$0.31	846,650	4.53	\$0.31
\$0.60 - \$1.00	289,000	1.29	\$0.92	289,000	1.29	\$0.92
> \$1.00	100,000	3.07	\$1.25	100,000	3.07	\$1.25
	<b>3,169,400</b>	<b>0.46</b>	<b>\$0.13</b>	<b>1,235,650</b>	<b>3.65</b>	<b>\$0.53</b>

## Notes and Debentures

The Company was debt free by March 31, 2017. All outstanding debentures had been converted, repaid in cash or repaid in Units in the Shares for Debt private placement (see *Equity and Debt Transactions - 2017* (b) and (c) above). At December 31, 2016 the Company had debentures with a face amount of \$728,000 (December 31, 2015 - \$1,016,000).

	Cash Due on Maturity				Maturity Date
	Balance at Dec. 31, 2016	Converted @ \$0.15/share	Repaid in \$0.32 Units	Repaid in Cash	
Amended Convertible Debentures with Warrants	\$228,000		\$170,000	\$58,000	8-21-2018
Amended Convertible Debentures with Warrants	385,000		334,000	51,000	10-22-2018
Amended Conversion Price Convertible Debentures	115,000	115,000			10-22-2018
<b>Total Debt</b>	<b>\$728,000</b>	<b>\$115,000</b>	<b>\$504,000</b>	<b>\$109,000</b>	

## Selected Quarterly Information

The selected quarterly information below is from the Company's condensed unaudited consolidated interim financial statements for the three and nine month periods ended September 30, 2017 and 2016.

Income Statement Summary	Quarter ended Sept 30		Nine months ended Sept 30	
	2017	2016	2017	2016
Revenue	\$ -	\$ 3,068	\$ 38,904	\$ 9,982
Cost of Revenue	-	15,228	38,414	49,580
Gross margin	-	(12,160)	491	(39,598)
Operating Expenses	1,179,779	450,646	2,357,923	1,624,122
<b>Loss from Operations</b>	<b>(1,179,779)</b>	<b>(462,806)</b>	<b>(2,357,433)</b>	<b>(1,663,720)</b>
Non-operating Income (Loss)	1,379,295	(263,422)	616,983	(727,066)
<b>Loss and comprehensive loss</b>	<b>199,517</b>	<b>(726,228)</b>	<b>(1,740,449)</b>	<b>(2,390,786)</b>
<b>Basic and diluted loss per share</b>	0.00	(0.03)	(0.04)	(0.09)

Loss from Operations in the first nine months of 2017 was approximately \$700,000 more than in 2016, all of which was due to additional expenses incurred in Q3, 2017. Of this increase, \$413,000 is attributable to non-cash share based compensation expense for stock option grants and for Deferred Share Unit expense for compensation grants to independent directors (News Release – August 16, 2017).

In Q3, the Company began the process of building a sales and marketing team with the hiring of two Vice-Presidents in the US; a VP of Worldwide Direct Sales and a VP of Distributor Sales. On August 1<sup>st</sup>, a Vice-President of Development and Operations was hired to re-build an in-house operations team, as development work has been out-sourced to contractors for the past 2 years for the 4-Chamber VMS Plus project.

The Company hired a consultant to conduct advanced market research in Q2 to determine the best positioning of the products in the Canadian marketplace and in Q3 the consultant began sales activities in Canada. The sales process to hospitals for capital expenditures can be a 6 to 9 month process, so we do not expect to see revenue before Q1 2018.

Non-operating income in the first nine months of 2017 includes a non-cash Derivative Liabilities Revaluation Adjustment income of \$757,118. This is primarily as a result of a Q3 closing share price which is lower than the share price at the time of the March, 2017 private placements, when the value of the 12.3M warrants issued with the Units resulted in a very large liability, which has since been revalued downwards with the lower share price. Under IFRS, the Company recognizes this reduction in the Derivative Liabilities value as income.

<b>Balance Sheet Summary</b>	<b>September 30, 2017</b>	<b>December 31, 2016</b>
Cash	\$2,265,425	\$191,282
Other Assets	297,241	481,220
<b>Total Assets</b>	<b>\$2,562,666</b>	<b>\$672,502</b>
Cash Liabilities	\$1,136,479	\$2,179,537
Derivative Liabilities	1,596,092	742,808
Total Liabilities	2,732,570	2,922,345
Total Shareholders Deficit	(169,904)	(2,249,842)
<b>Total Liabilities and Equity</b>	<b>\$2,562,666</b>	<b>\$672,503</b>

The increased cash balance is due to the March, 2017 Unit private placement ((a) above).

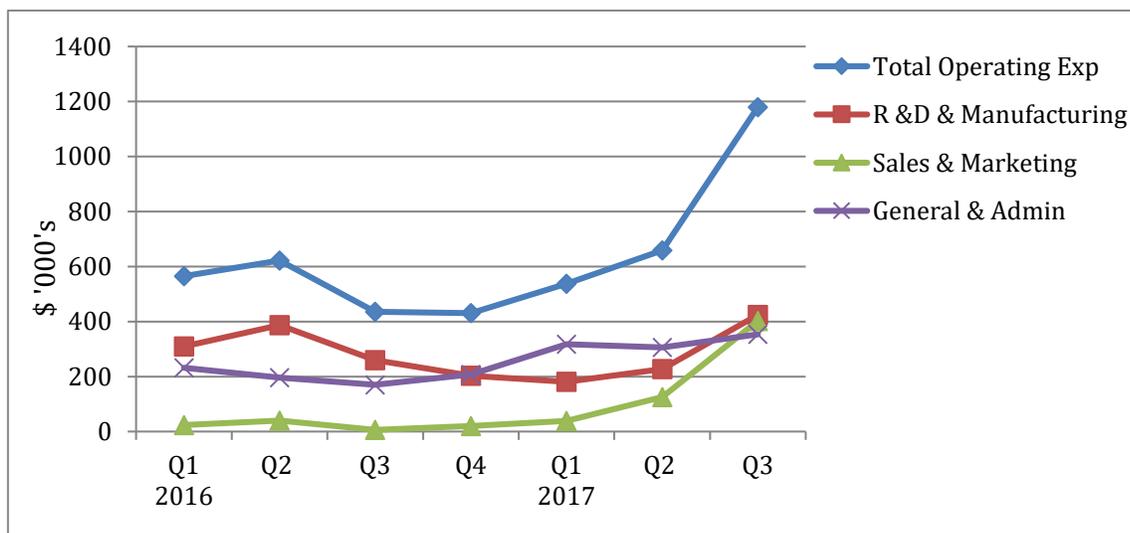
The Derivative Liability is *not* a liability that will ever require payment from the Company. It represents the value of the warrants themselves as at the period end. In time, the warrants will either be exercised, in which case the Company will receive the exercise price in cash, or the warrants will expire. The Company will never be required to make any payments with respect to the Derivative Liability balance.

The Derivative Liability on the balance sheet was \$1,596,092 at September 30, 2017 (December 31, 2016 - \$742,808), representing the fair market value of the outstanding warrants. This Derivative Liability balance is re-measured at each balance sheet date using a binomial model or Black-Scholes model, and can change significantly depending on a number of factors, including the trading price of the shares, the volatility of the trading prices, interest rates, and the remaining life of the outstanding warrants.

The closing share price at December 31, 2016 was \$0.12, while the share price at September 30, 2017 was \$0.245, therefore the value of the warrants outstanding at both dates will have increased, increasing the Derivative Liabilities balance. As well, 12,354,493 new warrants were issued with the March, 2017 private placement for an increase in the Derivative Liability of \$3,863,020. These warrants were valued at the time of the placement closing using a \$0.56 share price and have since been revalued downwards as the share price has fallen, resulting in a net revaluation adjustment reducing the Derivative Liability by \$757,118.

The exercise of 5,904,130 warrants in March through May resulted in a reduction of the Derivative Liability of \$1,827,074 and an increase in Share Capital of \$3,077,311.

## Operating Expenses



Operating expenses increased in Q3 year over year by from 2016 by approximately \$700,000. Of this increase \$400,000 is non-cash expense due to the issuance of stock options primarily to the new management team as part of their compensation packages, and the granting of Deferred Share Units to independent Directors (see NR August 16, 2016 for details).

Of the \$300,000 in cash expense increase, the majority of it is due to the ramping up of a sales and team to focus on launching sales of the new 4 Chamber 2DE VMS-PLUS product. On June 21<sup>st</sup> Ventripoint announced the appointment of Brian Leck as Vice-President of Direct Worldwide Sales and Mehran Mehrdash as Vice President, Worldwide Distributor Sales, both effective July 1, 2017. As well, a Canadian consultant was brought on to sell directly to Canadian hospitals. The budget process in most hospitals begins in April, so while the response to the 4-Chamber VMS-PLUS has been good, funding is not yet available for capital purchases in many hospitals.

Michael Slage was appointed as a consultant to the Company to be the primary liaison with the SEED group to help establish the Company in the Middle East. On November 15<sup>th</sup> the Company announced that it had signed a memorandum of understanding establishing a partnership with the SEED Group, a group of diversified companies owned and chaired by The Private Office of Sheikh Saeed Bin Ahmed Al Maktoum of Dubai, United Arab Emirates (NR – November 15, 2017). The partnership will initially focus on creating awareness with hospitals, doctors and officials of the unique features of the VMS-PLUS through research, conferences and opportunities designed to demonstrate its population health applications. Simultaneously, regulatory approvals for full clinical use will be obtained so sales efforts can begin in the new year.

Effective August 1<sup>st</sup>, Desmond Hirson was appointed as Vice-President, Development and Operations. Mr. Hirson is a seasoned executive with over 20 years of experience in commercializing medical devices and managing product development, manufacturing operations, regulatory and quality assurance. He was brought on to re-build the in-house manufacturing, regulatory compliance and development operations, which had been outsourced to Walled Networks since early 2016, for the development of the new 4-Chamber VMS-PLUS product.

## Non-Operating Income and Expense

The components of non-operating income and expense for the three and nine month periods ended September 30, 2017 and 2016 are as follows:

	Quarter ended Sept 30		Nine months ended Sept 30	
	2017	2016	2017	2016
<i>Finance costs:</i>				
Interest expense on notes and debentures	-	23,169	18,981	73,474
Accretion of derivatives issued with debentures	-	106,118	13,907	315,155
Transaction costs	-	-	132,218	-
Bank service charges and other	1,550	913	4,576	2,215
<i>Total finance costs</i>	1,550	130,203	169,682	390,844
Gain on shares issued for debt	-	-	(67,721)	
Other expense (income)	(17,639)		(17,639)	
Foreign currency differences	7,523	3,381	55,813	(2,167)
<b><i>Non-operating loss before Revaluation Adjustment</i></b>	<b>(8,566)</b>	<b>133,584</b>	<b>140,135</b>	<b>388,677</b>
Derivative liabilities revaluation adjustment	(1,370,729)	129,838	(757,118)	338,389
<b>Total non-operating loss (gain)</b>	<b>(1,379,295)</b>	<b>263,422</b>	<b>(616,983)</b>	<b>727,066</b>

Non-operating income in the first nine months of 2017 included a non-cash Derivative Liabilities Revaluation income adjustment of \$757,118. This Revaluation Adjustment is a non-cash item consisting of the decrease in the fair market value of the Company's outstanding warrants, calculated at the time of each warrant exercise (and convertible debenture retirement or conversion transaction), as well as at the end of the period.

With the retirement of all debentures in March, 2017, the finance costs were reduced to bank costs only in Q3.

Transaction costs in 2017 include 50% (the proportion allocated for the warrants) of the cash issuance costs for the private placement and Shares for Debt placement. Costs include legal, regulatory fees, and cash finders' fees. The other 50% of transaction costs are applied against share capital.

The gain on shares issued for debt is partly due to the repayment of \$504,000 in debentures from the Shares for Debt transaction on March 21<sup>st</sup>. The \$504,000 value of the Units (at \$0.32 per Unit) issued to the debenture holders for the \$504,000 face value of the repaid debentures, was lower than the fair value of the accreted debentures on the balance sheet (\$423,753) plus the fair value of the conversion features on those debentures (\$137,568), revalued at the date of the payout. This resulted in a gain of \$57,320. Also in March, \$109,000 of the debentures were repaid in cash, which resulted in a gain on retirement of the debentures of \$10,400.

The other income is the forgiveness of part of the Minimum Annual Royalty for 2016 owing to the University of Washington (see Contractual Cash Obligations below).

## Liquidity

<b>Liquid assets and liabilities</b>	<b>As at</b>	
	<b>September 30, 2017</b>	<b>December 31, 2016</b>
Cash and equivalents	2,265,425	191,282
Amounts receivable	75,356	128,922
Inventory	26,913	11,969
<i>Current liquid assets</i>	2,367,694	332,173
Accounts payable and accrued liabilities	1,136,479	1,522,112
Interest payable	-	21,401
Debentures & notes - cash due at maturity	-	728,000
<i>Cash liabilities</i>	1,136,479	2,271,513
<b>Working capital (deficit)</b>	<b>1,231,216</b>	<b>(1,939,340)</b>

The Unit private placement on March 23, 2017 raised cash of \$3,359,020, allowing the Company to reduce payables by \$386,000 and repay \$130,000 of debentures and interest payable in cash. The Shares for Debt private placement transaction on March 21, 2017 repaid \$504,000 of debentures, which, along with the conversion of \$115,000 of debentures, means the Company is now debt free, and the Company's net liquid assets at September 30, 2017 are up by almost \$3.1M since the beginning of the year. At September 30, 2017 accrued liabilities included \$365,000 of accrued but unpaid compensation payable to the Company's CEO. Accounts receivable consist entirely of refundable Canadian sales tax, receivable in early 2018.

## Contractual Cash Obligations

The Company has the following contractual cash obligations, payable in US\$, as of November 29, 2017:

	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020 - 2025</b>	<b>Total</b>
University of Washington Technology License					
Minimum Annual Royalty	\$ 44,860	\$ 6,227	\$ 6,227	\$ 37,362	\$94,676
Premises Lease, Toronto, ON	-	43,681	44,886	129,538	\$218,105
<b>Total contractual commitments for the period in CDN Equivalent \$</b>	<b>\$44,860</b>	<b>\$49,908</b>	<b>\$51,113</b>	<b>\$166,900</b>	<b>\$312,781</b>

The Minimum Annual Royalty (MAR) under the Technology License Agreement with the University of Washington is currently being amended, retroactive to September, 2016, to US\$5,000 from US\$50,000. The Royalty payable is the higher of 1.5% of sales, net of direct distribution costs, (amended from 3% of sales) and the MAR.

On October 1, 2017 the Company entered into a 5 year lease for new 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.

## **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 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**

In May, 2015 the Company received clearance from the FDA to market its application in the United States for the expanded Indications for Use of its VMS product which states; "The VMS system is indicated for use where RV (right ventricle) volumes and ejection fractions are warranted or desired." This means physicians in the U.S. can now use the VMS on patients that they believe will benefit from assessment of RV function, without being limited to a specific condition.

In March, 2017, the Company announced that it has received a license from Health Canada for the new VMS-PLUS machine and the 4-chamber (4C) heart analysis system. This is an expansion of the VMS heart analysis product to include right atrium (RA), left atrium (LA) and left ventricle (LV) chambers of the heart. The VMS was already licensed in Canada for use for the right ventricle (RV). 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 RV VMS product has the European CE Mark.

**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 condensed consolidated interim financial statements for the nine month periods ended September 30, 2017 and 2016, have been prepared in accordance with International Accounting Standard 34 - *Interim Financial Reporting*. Accordingly they do not include all disclosures which would otherwise be required in a complete set of financial statements and should be read in conjunction with the annual audited financial statements for the year ended December 31, 2016, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The Company has applied the same accounting policies and methods of computation in its interim condensed consolidated interim financial statements as in its 2016 annual audited consolidated financial statements. 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 are revalued at each balance sheet date using the Black-Scholes option pricing model or specialized binomial models required to reflect the impact of the acceleration of the expiry date under certain circumstances. 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 8 and 9 of the September 30, 2017 condensed interim 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).