

**MANAGEMENT DISCUSSION AND ANALYSIS FOR CVR MEDICAL CORP.  
FOR THE YEAR ENDED DECEMBER 31, 2018  
PREPARED AS OF AUGUST 21, 2019**

**Contact Information**

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**BACKGROUND**

*This discussion and analysis of financial position and results of operations is prepared as at August 21, 2019 and should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2018, of CVR Medical Corp. (“CVR Medical” or the “Company”). The audited consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRS”). Except as otherwise disclosed, all dollar figures included therein and the following management discussion and analysis (“MD&A”) are quoted in U.S. dollars. Additional information relevant to the Company’s activities can be found on SEDAR at [www.sedar.com](http://www.sedar.com).*

*The Company’s trading symbol on the TSX Venture Exchange is “CVM.V”. The content of this MD&A has been approved by the board of directors of the Company (the “Board” or “Board of Directors”), on the recommendation of its Audit Committee.*

**CAUTIONARY STATEMENT ON FORWARD LOOKING INFORMATION**

This Management’s Discussion and Analysis may include forward-looking statements with respect to business plans, activities, prospects, opportunities and events anticipated or being pursued by the Company and the Company’s future results. Although the Company believes the assumptions underlying such statements to be reasonable, any of the assumptions may prove to be incorrect. The anticipated results or events upon which current expectations are based may differ materially from actual results or events. Therefore, undue reliance should not be placed on such forward-looking information. A number of risks and uncertainties could cause our actual results to differ materially from those expressed or implied by the forward-looking statements, including: (1) a downturn in general economic conditions in North America and internationally, (2) the uncertainty as to product development and commercialization milestones, (3) the uncertainty as to the regulatory approval of the Company’s technology or intellectual property, (4) the risk that the Company does not execute its business plan, (5) inability to retain key employees, (6) inability to finance operations and growth, and (7) other factors beyond the Company’s control.

Forward-looking statements speak only as of the date of this MD&A and actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors. Investors should not place undue reliance on forward-looking statements as the plans, intentions or expectations upon which they are based may not occur. The Company does not assume responsibility for the accuracy and completeness of the forward-looking statements set out in this MD&A and, subject to applicable securities laws, does not undertake any obligation to publicly revise these forward-looking statements to reflect subsequent events or circumstances. The forward-looking statements contained herein are expressly qualified by this cautionary statement.

## **OVERALL PERFORMANCE AND RESULTS OF OPERATIONS**

CVR Medical Corp. (the “Company” or “CVR Medical”) was previously involved in the acquisition, exploration and development of mineral properties. Effective September 16, 2016, the Company acquired patents (the “Patents”) underlying a diagnostic device developed by CVR Global Inc. (“CVR Global”) for the detection and measurement of carotid arterial stenosis (the “Device”) in consideration for 7,000,000 common shares in the capital stock of the Company (the “Transaction”). Additionally, CVR Global and the Company formed an equal part joint operation to commercialize the Device, pursuant to which the Company contributed the Patents and working capital and CVR Global contributed certain additional patents and intellectual property underlying the Device, as well as management know-how and marketing expertise.

The joint operation is in the medical industry focused on the commercialization of proprietary subsonic, infrasonic, and low frequency sound wave analysis technology and has patents to a diagnostic device designed to detect and measure carotid arterial stenosis.

On June 1, 2018, the Company and CVR Global entered into a restructuring agreement (which we refer to as the “Restructuring Agreement”) whereby, upon closing, which occurred in November 2018, the Company acquired CVR Global’s 50% interest in the Joint Venture and the Joint Venture was terminated in favor of a new commercialization arrangement of the CSS device in the Company’s newly formed wholly-owned subsidiary, CVRM, Inc. (which we refer to as CVRM). This new structure is intended to be a more conventional milestone driven equity distribution and royalty agreement. Pursuant to this new arrangement, CVR Medical will be responsible through its wholly owned subsidiary CVRM for the commercialization of the CSS device and CVR Global is responsible for managing all R&D, clinical pathway, governmental and regulatory filings including the submission with the FDA and maintaining the IP portfolio on behalf of CVRM. The term of this commercialization agreement is 20 years.

As consideration under the Restructuring Agreement, on November 30, 2018, the Company issued 30 million common shares to CVR Global which were placed into escrow to be released upon achievement of four key milestones:

- 3 million shares were released from escrow upon formal approval of the Restructuring Agreement (issued on November 1, 2018);
- 2 million shares were released upon the FDA submission of the CSS device which occurred in January 2019 (issued on January 16<sup>th</sup>, 2019);
- 10 million shares will be released upon receiving FDA Approval/Clearance of the CSS device; and;

- 15 million shares will be released if CVR Medical achieves \$50 million in sales of the CSS device within two years post clearance.

In addition to the equity consideration, CVR Global will also receive a 7% royalty on all CSS devices sold paid quarterly (in arrears) with a 3% royalty on all consumables. The Restructuring Agreement has been approved by the Board of Directors, the Company's shareholders, and the TSX Venture Exchange, and has closed as of the date of this management's discussion and analysis.

## **Corporate Overview**

CVR Medical Corp. was incorporated on December 10, 1980 under the British Columbia Business Corporations Act and is engaged in an equal parts joint operation with CVR Global, Inc. ("CVR Global").

CVR Global was incorporated under Michigan law in 2007 and operates in the medical industry, focused on the commercialization of a proprietary sub-sonic, infrasonic, and low frequency sound wave analysis technology.

The Company's registered office is Suite 409 – 221 West Esplanade, North Vancouver, British Columbia, V7M 3J3. The Company's corporate headquarters are located at 4664 Sierra View Drive, Denver, North Carolina 28037.

## **Business Overview**

The relentless demand for healthcare services will continue into the foreseeable future, fueled by population growth and increased longevity. Diagnostic testing is an integral part of the healthcare system, providing essential and timely information to enable the providers and patients to make the right clinical decisions. Demand for access to quicker and more accurate diagnosis is rapidly rising, and will contribute substantial savings to the medical system.

Stroke arises due to interruptions in the blood supply to the brain, either due to the rupture or blockage of blood vessels which leads to the death of brain cells. Stroke is one of the major causes of death worldwide, with higher likelihood as age increases. According to the World Health Organization (WHO), stroke accounts for 6.2 million deaths annually. As per the Centers for Disease Control and Prevention (CDC), stroke leads to 1 out of every 20 deaths, costing roughly \$33 billion each year in the U.S. Hence, there is an impending need for early diagnostic devices and therapeutics to assist the healthcare provider in preventing stroke. The global stroke diagnostics and therapeutics market accounted for US\$21.5 billion in 2015 and is expected to reach US\$31 billion by 2021, growing at a compounded annual growth rate of approximately 7.0% between 2015 and 2021.

Carotid arterial stenosis is the narrowing of the carotid arteries, usually caused by atherosclerosis. Atherosclerosis is the buildup of cholesterol, fat and other substances traveling through the bloodstream, such as inflammatory cells, cellular waste products, proteins and calcium. These substances stick to the blood vessel walls over time, and combine to form a material called plaque. Plaque buildup can lead to narrowing or blockage in the carotid artery which, when significant, can put an individual at increased risk for Ischemic stroke.

## **The Carotid Stenotic Scan (CSS) Device**

The Company's Carotid Stenotic Scan (CSS) Device listens to sound waves produced by the flow of blood within the carotid arteries, analyzing the data to provide the clinician with a report detailing the level of narrowing present. The original sensors were developed by our contractor CVR Global under a Cooperative Research and Development Agreement (CRADA) with the Army Research Lab (ARL). These proprietary sensors were developed to enhance the acoustic characteristics of the blood flow under analysis. The low frequency sound patterns are then analyzed by CVR's proprietary technology. The CSS device is designed to be a noninvasive, cost-effective tool to assess the direct risk factor for arterial disease. Further, the Device is cost effective when compared to other arterial assessment modalities within the healthcare field which requires operation by trained clinical experts and interpretation by medical specialists.

Our contractor, CVR Global on our behalf has engaged Kyle Vos Strache to institute a comprehensive IP policy to cover all aspects of the CSS device as it prepares to go to market. Kyle is a registered patent attorney and works with clients from large multinational corporations to bootstrapping entrepreneurs to evaluate their products to maximize breadth and coverage of intellectual property portfolios throughout the world. The IP includes one issued US patent, US 9,101,274, generally covering a sensor pod for sensing acoustic signals, and its European Counterpart, which parallels the allowed US case and is currently pending. A continuation-in-part, Application No. 14/803,389 is also pending, with a priority date extending back to June 24, 2010. In June of 2015, CVR filed two applications covering the Yoke, utilized for holding the sensors and positioning on a patient, and for methods of quantifying and detecting sounds in the carotid artery. Both the yoke and method applications were utilized as priority applications for PCT applications filed in June of 2016 and entered into national stages in several countries at the end of 2017. In June of 2016, CVR filed five additional provisional patent applications covering several aspects of the CSS device to expand the coverage of the CSS device, including applications covering improvements and new features for the CSS device. Of these five applications, four were converted into PCT applications in 2017 and await national stage entry in late 2018. In December of 2016, CVR filed an additional provisional application directed towards a new sensor pod that is in development, which was converted to a PCT application in December of 2017. In January of 2017, CVR filed two design patents, one directed towards the device cart itself, and the second to a version of the Yoke for positioning sensors on a patient, these are both pending in the United States. In June of 2017, additional provisional patents were filed on new features and new embodiments not previously disclosed. CVR is evaluating these for conversion in 2018 or to file new provisional applications on technologies that have yet to be disclosed. CVR will continue to develop and file for new IP as it is developed.

## **Clinical Trials and Regulatory Status**

During the past year our contractor, CVR Global has concluded the initial pivotal trials necessary to support the CSS De Novo submission. Using the data collected, the CSS was submitted to the FDA for US market approval in January 2019. Additionally, CVR took actions to expand their clinical footprint, receiving IRB Board approval to conduct clinical research at both the Mayo Clinic and Wake Forrest Baptist Health. These locations will be used to provide any additional data which the FDA may request, as well as support a brand awareness by association with US centers of excellence within the cardiovascular space.

In 2012, CVR Global conducted clinical trials at the William Beaumont Hospital in Royal Oak, Michigan. Over 200 patients were tested, producing comparative results representing equivalencies to the current gold-standard, Duplex Doppler Ultrasound. The CSS was designed as a cost-effective way to provide the clinician with the data necessary to provide early stage medical care to combat carotid artery disease and prevent downstream events, such as stroke. CVR Leadership is working closely with leading scientific minds, top vascular clinicians, and regulatory advisors to bring a safe and effective device to market which will meet the needs of all stakeholders within the healthcare system.

In 2016, our contractor CVR Global on our behalf completed an agreement with Thomas Jefferson University Hospital in Philadelphia for the design and conduction of its current, leading to final phase, clinical trials for its “Carotid Stenotic Scan (CSS)” device under the guidance of Dr. David J. Whellan. Dr. Whellan is the Executive Director of the Jefferson Clinical Research Institute (JCRI) and Principal Investigator of the Jefferson Regional Clinical Center for the NIH HF Network, one of nine centers across the United States selected to participate in a series of novel heart failure clinical trials. Recognized as preeminent in the cardiovascular healthcare field, his extensive clinical research has produced over 175 peer-reviewed publications on cardiovascular disease.

By November 2017, over 300 patients had been enrolled in the tertiary clinical trials conducted at Thomas Jefferson University Hospital (“TJU”). During June 2017, TJU-Jefferson Clinical Research Institute issued an initial clinical trial summary report, communicating the overall progress of the CSS within the study, and CVR leadership believed the clinical justification for the CSS had progressed exceptionally from the report data presented.

On January 23, 2018, our contractor CVR Global on our behalf commenced clinical data acquisition for the Carotid Stenotic Scan (CSS) at Henry Ford Hospital in Michigan, overseen by Dr. Judith Lin, Senior Staff Surgeon and Medical Director of Henry Ford’s Clinical Vascular Laboratory. The Clinical Vascular Laboratories at Henry Ford performs over 15,000 noninvasive vascular tests annually in their state-of-the-art vascular laboratories accredited by Intersocietal Accreditation Commission.

The wireless Carotid Stenotic Scan (CSS) device was finalized in 2017, and during February 2018, our contractor CVR Global on our behalf placed two additional wireless CSS devices into clinical trials at Methodist Hospital, within the Thomas Jefferson University Hospital System. Combined with the three wireless CSS devices already in use, this increased the volume of clinical data that was used in the FDA submission to acquire market clearance.

In February 2018, our contractor CVR Global on our behalf received Internal Review Board (IRB) approval by The Cleveland Clinic, sanctioning CVR to conduct clinical trials using the Carotid Stenotic Scan (CSS) device. The trial will be overseen by Primary Investigator Dr. Heather Gornik, Medical Director of the Non-Invasive Vascular Laboratory in the Cleveland Clinic Department of Cardiovascular Medicine. Cleveland Clinic was voted the number two best hospital in the United States in 2018, according to U.S. News & World Report. With more than 1,400 beds on their main campus and 4,435 beds system-wide, Cleveland Clinic is one of the leading clinical research institutions in the United States.

On March 5, 2018, our contractor CVR Global on our behalf commenced pivotal trials for the Carotid Stenotic Scan (CSS) device, the final phase of clinical substantiation to support the upcoming FDA submission. Thomas Jefferson University Hospital (Philadelphia, PA) will act as the primary pivotal trial location, with Cleveland Clinic (Cleveland, OH) and Henry Ford Hospital (Detroit, MI) acting as supplementary sites. The Company plans to expand the footprint as other locations come online, increasing the speed of data procurement and shortening the timeframe to submission.

We announced on May 9, 2018 that our contractor, CVR Global was in receipt of official meeting minutes for their Pre-Submission meeting on March 23, 2018 with the FDA regarding the CSS device and its upcoming FDA submission for market release. The purpose of the meeting was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing. Importantly, CVR Global on our behalf has retained Duval & Associates and JD Lymon as counsel guiding the Company through both the FDA and reimbursement submissions.

In an effort to bolster the clinical footprint using the CSS in a research capacity, in January 2019, our contractor, CVR Global on our behalf received IRB approval by The Mayo Clinic, sanctioning us to conduct clinical trials using the CSS device. We have contracted with Mayo Clinic Gonda Vascular Center to conduct clinical trials using the CSS device. Currently In the U.S. News & World Report rankings of top hospitals, Mayo Clinic is the No.1 hospital overall and No.1 in more specialties than any other hospital in the nation. Trials will be managed by Primary Investigator Thanila A. Macedo, MD. A Mayo Clinic radiologist of eighteen years, Dr. Macedo's interest in noninvasive diagnostics aligns with CVR's goal of delivering a novel device that will alter the way carotid artery stenosis is examined and treated.

In April 2019, our contractor CVR Global and Wake Forest Baptist Medical Center (WakeForest Neuro Ultrasound Lab) at the medical center, based in Winston-Salem, North Carolina, announced they are working to finalize plans for a clinical study, which will gather comparative clinical and user experience data on the novel CSS device. Wake Forest Baptist Medical Center is a nationally prominent academic medical center in Winston-Salem, with an integrated health care network that incorporates hospitals, clinics, physician practices, diagnostic centers and other primary and specialty care facilities serving the residents of 24 counties in northwest North Carolina and southwest Virginia. The medical school is ranked by U.S. News & World Report as one of the nation's best, just as the hospital has been since 1993. Under the leadership of Dr. Charles Tegeler, Medical Director of the Neuro Ultrasound lab and Ward A Riley Ultrasound Center Wake Forest Neuro Ultrasound Lab continues to be a world leader in clinical practice, education, and research in neurosonology. This lab provides more than 20 years of experience as an ultrasound reading center for multicenter clinical trials. The clinical trial will be managed by Primary Investigator Aarti Sarwal, M.D. Dr. Sarwal is an Associate professor of Neurology at Wake Forest Baptist Health Center and is currently the Medical Director of Neurocritical Care Unit. Dr. Sarwal received her medical training from Government Medical College, Patiala (India), Neurology Residency at University of Missouri, and Neurocritical Care fellowship at Cleveland Clinic, OH. She is a passionate educator and the Co-Director of the Ultrasound Curriculum at Wake Forest School of Medicine. Dr. Aarti's education, research and clinical interests focus on ultrasound applications in neurology and non-invasive multimodality monitoring in neurocritical care patients. She is also a faculty for several national and international Ultrasound courses and participates in several clinical trials as an ultrasound expert. She is listed by US News and World Report among Best Doctors.

Medical devices are subject to regulatory clearances within individual markets and jurisdictions. As such, they are evaluated for compliance with established consensus standards. When a new technology is involved, in order to get USA clearance through the FDA approval process. With a non-invasive / non-emitting medical device that possesses a lower level of risk typically the 510(k) process would be followed in which a manufacturer must identify an existing “predicate” device from which to compare the new technology. If no clear predicate device is identified then the submission must be conducted under the De Novo submission process, or the PMA process for higher risk devices. Clearance in the USA is potentially the most important to obtain and maintain due to the size of that market and its importance in terms of practice. Based on prior communication with the FDA and input provided by key regulatory advisors, CVR had considered the potential for either a 510k, De Novo, or PMA submission; with the De Novo being the preferred pathway. During the meeting, these topics were discussed and in follow-up communication the FDA team stated the CSS was sufficiently different from other devices on the market today to decide the De Novo pathway was best suited, which is designed for low to moderate risk novel devices. As found on the FDA website, the number of FDA Approvals/Clearances in 2017 for each of the three categories; PMA, De Novo and 510(k) were 1,747, 31 and 3,175 respectively. The average time to a decision by the FDA in 2017 for each of the three categories PMA, De Novo and 510(k) were 262 days, 133 days and 177 days respectively.

#### *FDA Status*

On January 3, 2019, we announced our contractor CVR Global on our behalf submitted our CSS device to the FDA as a De Novo application. This submission was made following receipt of official meeting minutes for our Pre-Submission meeting on March 23, 2018 with the FDA regarding the CSS device (the purpose of which was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing). Our contractor, CVR Global on our behalf retained Duval & Associates and JD Lymons as counsel to guide us through both the FDA process as well as to develop the CMS CPT reimbursement pathway. Medical devices are subject to regulatory clearances within individual markets and jurisdictions. As such, they are evaluated for compliance with established consensus standards. With a non-invasive / non-emitting medical device that possesses a lower level of risk typically the 510(k) process would be followed in which a manufacturer must identify an existing “predicate” device from which to compare the new technology. If no clear predicate device is identified then the submission must be conducted under the De Novo submission process, or the PMA process for higher risk devices. Based on prior communication with the FDA and input provided by key regulatory advisors, we had considered the potential for either a 510k, De Novo, or PMA submission; with the De Novo being the preferred pathway. During the March 23, 2018 meeting, these topics were discussed and in follow-up communication the FDA team stated the CSS device was sufficiently different from other devices on the market today to decide the De Novo pathway was best suited, which is designed for low to moderate risk novel devices.

On May 31st 2019 leadership from both CVR Medical, and its contracted manufacturing partner CVR Global as well as representatives from both Hyman, Phelps & McNamara, P.C. and J.D. Lymons attended a meeting with the US Food and Drug Administration (FDA) to address questions and deficiencies put forth regarding the January 2019 de novo submission of the Carotid Stenotic Scan (CSS1) Device. The meeting was also attended by the expert review team assigned to the submission by the FDA.

The purpose of the meeting was to confirm that CVR's new proposed "Indications for Use" were on target, align on the approach for the additional multi-center clinical trials, and clarify the new statistical requirements. The meeting provided clarification regarding necessary action items associated with the new agreed upon clinical substantiation plan moving forward which includes the following patient criteria: patients who are considered 'at-risk' based on age of 65 years or older and with at least one risk factor of hypertension, hyperlipidemia, coronary artery disease/peripheral artery disease, diabetes mellitus, family history of early cardiovascular disease and/or tobacco use, as well as alignment on proper justification for the accuracy and usage of the CSS within the healthcare setting.

Subsequent to the meeting with the FDA, representatives from our contractor CVR Global on our behalf revised the Clinical Implementation Plan and corresponding protocol in deploying new devices across CVR's expanded clinical trial footprint. By placing new devices in four "Centers of Excellence"; Thomas Jefferson University Hospital, Cleveland Clinic, Mayo Clinic, and Wake Forrest Baptist Health, our Contractor CVR Global intends to capture the required clinical substantiation (Est. ~240 Patients) as quickly and efficiently as possible. Final analysis of the updated clinical study will be conducted by an independent third party, as required for evaluation by the FDA. Once the necessary clinical data is acquired CVR Global on our behalf will resubmit the De Novo Application to the FDA for US market approval of the CSS. The exact impact on the overall timeline to market approval, and subsequent sales, is still underdetermined. By leveraging the larger clinical footprint, along with the knowledge gained from our meetings with the FDA, our confidence that, upon the company successfully raising the required working capital necessary to complete the new clinical trials and other developmental work, we could re-submit the De Novo application late in Q4/2019 with a possible market launch in 2H/2020.

Lastly, while the company recognizes it announced in January 2019, that it had completed safety testing by TUV, an additional program of independent EMC & Safety testing will be conducted in parallel to the new clinical trials. This testing will be conducted by TUV in accordance with the IEC 60601-1 standard and will be based on the revised essential performance statement and necessary parameters identified by the FDA in their deficiency letter.

## **Subsequent Events**

### *Trading Halt*

On May 6<sup>th</sup>, 2019 the Company received notification that The British Columbia Securities Commission (BCSC) has issued a cease trade order (CTO) in regards to trading of the Company's securities, due to the Company not filing its audited financial statements and related management discussion and analysis for the 2018 fiscal and calendar year in a timely manner. Trading in the Company's securities will remain halted until the completion of the filing.

### *Resignation of Directors and Officers*

On May 6<sup>th</sup>, 2019, James D'Orta, M.D., resigned from our Board of Directors effectively immediately and directors Wayne Hellman and Joel Kanter and officers Tom Harris, Chief Financial Officer and Marc S. Lubow, Executive Vice President tendered their resignations from their respective positions with CVR Medical effective August 20<sup>th</sup>, 2019 due to substantial disagreements with the CEO.



## RESULTS OF OPERATIONS

At December 31, 2018, the Company held assets recorded at \$1,382,543, consisting of \$74,742 in cash, prepaid expenses of \$67,501, tax recoverable of \$31,375, equipment of \$711, and intangible assets of \$1,077,555.

We have never been profitable and have incurred net losses in each year since our inception. We incurred net losses of \$7.4 million and \$6.6 million for the year ended December 31, 2018 and 2017, respectively. As of December 31, 2018, our accumulated deficit was \$25.4 million. We expect to continue to incur substantial net losses and negative cash flows from operations until we commercialize our CSS Device. We intend to make a significant investment in building our U.S. commercial infrastructure and in recruiting and training our sales representatives. We also intend to continue to make significant investments in research and development to expand our CSS Device for other diagnostic applications. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate sufficient revenue to cover our operating expenses and growth strategy, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of CSS device. We face a variety of challenges and risks, which we will need to address and manage as we pursue our strategy, including our ability to develop and retain an effective sales force and achieve market acceptance of CSS device by the medical community.

Because of the numerous risks and uncertainties associated with our commercialization efforts, as well as research and clinical development activities, we are unable to predict the timing or amount of increased expenses, or when, if ever, we will be able to achieve or maintain profitability. Even if we commercialize the CSS Device, we may not become profitable. If we fail to become profitable or are unable to sustain profitability, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

The components of the Company's results of operations are comprised of:

- **Expenses other than research and development** - Consisting primarily of consulting (fees paid for personnel and various other services contracted on behalf of the Company), office and general expenses, professional fees, share-based compensation, foreign exchange gain/loss and transfer agent and filing fees. These costs have been incurred primarily to obtain financing and fund research and development efforts effort to prepare for FDA submission.
- **Research and development** – Prior to the closing of the Restructuring Agreement on October 31, 2018, our research and development expenses are comprised of payments to CVR Global for research and development activities performed on behalf of the equal part joint operation owned by the Company and CVR Global. Subsequent to the closing of the Restructuring Agreement, our research and development expenses are comprised of expenditures incurred to CVR Global pursuant to the Commercialization Agreement.

Research and development expenses consist primarily of, compensation, consulting services, outside services, materials, engineering, product development, quality assurance, clinical trial and regulatory expenses incurred in conjunction with preparation for FDA submission.

- **Company write-off of advances to CVR Global** - CVR Global and the Company are involved in a joint operation to commercialize the Device, pursuant to which the Company contributed patents and working capital and CVR Global contributed certain additional patents and intellectual property underlying the CSS Device, as well as management know how and marketing expertise, for an initial equal equity interest by both parties in the joint operation. CVR Global performs research and development activities on behalf of the joint operation and the Company has provided all funding for research and development activities to date. Amounts advanced by the Company on behalf of CVR Global have been written off when considered to be uncollectible.

## SUMMARY OF ANNUAL INFORMATION

The following table sets forth selected financial information of the Company for the last three fiscal years. This financial information is derived from the audited financial statements of the Company:

| Item                                  | Year ended<br>December 31,<br>2018 | Year ended<br>December 31,<br>2017 | Year ended<br>December 31,<br>2016 |
|---------------------------------------|------------------------------------|------------------------------------|------------------------------------|
| Total Revenue                         | Nil                                | Nil                                | Nil                                |
| Total Loss from Continuing Operations | \$6,485,570                        | \$3,976,287                        | \$1,874,318                        |
| Net Loss in Total                     | \$7,441,928                        | \$6,552,238                        | \$2,271,620                        |
| Net Loss on a per Share Basis         | \$0.10                             | \$0.11                             | \$0.08                             |
| Total Assets                          | \$1,382,543                        | \$1,723,269                        | \$1,214,520                        |
| Total Long Term Financial Liabilities | Nil                                | Nil                                | Nil                                |
| Cash Dividends Declared per Share     | Nil                                | Nil                                | Nil                                |

The large increase in loss from continuing operations and net loss during the year ended December 31, 2017 as compared to the year ended December 31, 2016, was mainly attributable to an increase in research and development costs of \$1,127,188 relating to the development of the CSS device as well as an increase in consulting fees of \$884,898, and office and general expenses of \$1,078,952, offset by a decrease in share-based compensation of \$661,354. The increase in total assets was a result of an increase in cash from the issuance of shares for cash pursuant to private placements, and the exercise of stock options and warrants.

The increase in net loss for the year ended December 31, 2018, from 2017 of \$7,441,928 versus \$6,552,238, respectively, was mainly comprised of:

- Increase in professional fees of \$616,330 – Due to increase in legal fees;
- Increase in research and development expenses of \$861,856 – Due to additional expenditures required to prepare the Device for FDA approval;
- Increase in share-based compensation of \$1,038,211 – Due to the vesting of common share consideration to CVR Global pursuant to the Restructuring Agreement; and
- Increase in interest expense of \$152,591 – Primarily due to funding received during the period from interest-bearing notes. On July 25, 2018, August 6, 2018, and September 4, 2018, the Company entered into promissory notes for US\$25,000, US\$200,000 and \$150,000, respectively, which bear interest at 30% per annum.

These decreases were partially offset by the following:

- Decrease in write-off of advance to CVR Global Inc. of \$1,775,251 – Due to less funds provided for the joint operation on behalf of CVR Global.
- Decrease in office and general of \$62,896 - Due primarily to reduced investor relation fees;

## SUMMARY OF QUARTERLY RESULTS

The following is selected financial information from the Company's eight most recently completed fiscal quarters:

|                                   | <b>4<sup>th</sup> Qtr<br/>Ended<br/>12-31-18</b> | <b>3<sup>rd</sup> Qtr<br/>Ended<br/>9-30-18</b> | <b>2<sup>nd</sup> Qtr<br/>Ended<br/>6-30-18</b> | <b>1<sup>st</sup> Qtr<br/>Ended<br/>3-31-18</b> | <b>4<sup>th</sup> Qtr<br/>Ended<br/>12-31-17</b> | <b>3<sup>rd</sup> Qtr<br/>Ended<br/>9-30-17</b> | <b>2<sup>nd</sup> Qtr<br/>Ended<br/>6-30-17</b> | <b>1<sup>st</sup> Qtr<br/>Ended<br/>3-31-17</b> |
|-----------------------------------|--|---|---|---|--|---|---|---|
| Total Revenues                    | \$Nil  | \$Nil   | \$Nil   | \$Nil   | \$Nil  | \$Nil   | \$Nil   | \$Nil   |
| Operating Income (Loss)           | (\$3,609,758)                                    | (\$492,022)                                     | (\$1,535,212)                                   | (\$848,578)                                     | (\$687,290)                                      | (\$802,678)                                     | (\$896,466)                                     | (\$1,589,853)                                   |
| Total Net Income (Loss)           | (\$3,122,323)                                    | (\$1,196,764)                                   | (\$1,733,746)                                   | (\$1,389,095)                                   | (\$1,439,607)                                    | (\$1,049,357)                                   | (\$1,643,525)                                   | (\$2,419,749)                                   |
| Total Net Income (Loss) Per Share | (\$0.04)   | (\$0.02)  | (\$0.02)  | (\$0.02)  | (\$0.02)   | (\$0.02)  | (\$0.03)  | (\$0.05)  |

Factors causing significant variations in quarterly results are as follows:

The decrease in net loss for the quarter ended June 30, 2017, was mainly comprised of a decrease in consulting fees, office and general expenses, and share-based compensation.

The decrease in net loss for the quarter ended September 30, 2017, was mainly comprised of a decrease in research and development costs and a decrease in write-off of advance to CVR Global, Inc.

The increase in net loss for the quarter ended December 31, 2017, was mainly comprised of a increase in research and development costs and an increase in write-off of advance to CVR Global, Inc.

The net loss for the quarter ended March 31, 2018, was relatively consistent with the prior quarter ended December 31, 2017.

The increase in net loss for the quarter ended June 30, 2018, was mainly comprised of an increase in research and development costs and an increase in write-off of advance to CVR Global, Inc.

The decrease in net loss for the quarter ended September 30, 2018, was mainly comprised of a decrease in research and development costs, offset by an increase in write-off of advance to CVR Global, Inc.

The increase in net loss for the quarter ended December 31, 2018, was mainly comprised of an increase in consulting fees, office and general, research and development costs, and share-based compensation to CVR Global, Inc.

#### ***Fourth Quarter Results***

During the three months ended December 31, 2018, the Company recorded an operating loss of \$3,609,758 and a net loss of \$3,122,323, compared to the three months ended December 31, 2017, where the Company recorded an operating loss of \$687,290 and a net loss of \$1,439,607. The increase in operating loss and net loss was mainly due to an increase in share-based compensation of \$1,239,539, and increase in research and development costs of \$703,407, an increase in consulting fees of \$175,963, an increase in office and general of \$420,892, an increase in professional fees of \$504,950, and an increase in interest expense of \$108,231.

#### **LIQUIDITY AND CAPITAL RESOURCES**

The development and commercialization of the Carotid Stenosis Scan device that CVR Medical is involved in will depend on the Company's ability to obtain additional financing through the sale of its securities or from third party loans. There is no assurance that such financing will be available when required by or under terms favorable to the Company.

At December 31, 2018, the Company had \$74,742 of cash and cash equivalents on hand, which may not be sufficient to cover expected administrative expenses and expenditures involved in the development of the CSS device in the coming months. In view of these circumstances, the Company still expects to secure funding from several sources in 2019, including from financing through private placements, exercise of options and warrants and third-party loans, and will continue to explore all available options to secure additional funding including equity financing and strategic partnerships. Nevertheless, it is not possible to determine with any certainty the success or adequacy of these initiatives.

During the year ended December 31, 2018, the Company received proceeds from promissory notes payable of \$796,952, net proceeds from the issuance of units of \$4,028,016 and proceeds from the issuance of common shares pursuant to the exercise of warrants of \$871,812. Additionally, the Company repaid promissory notes payable of \$771,952 during the year ended December 31, 2018.

On January 17, 2019, the Company closed a private placement of 4,820,000 units at CDN\$0.25 per unit for gross proceeds of CDN\$1,205,000. Each unit consists of one share of common stock of the Company and one transferable common stock purchase warrant. Each full warrant is exercisable at a price of CDN\$0.36 per share until January 17, 2024. The Company incurred issuance costs of CDN\$128,483 and issued a total of 359,800 compensation warrants. The compensation warrants are exercisable into units (“Broker Units”) at \$0.25 per unit until January 17, 2024. Each Broker Unit consists of one common share and one common stock purchase warrant (“Agent’s Warrant”). Each Agent’s Warrant is exercisable at \$0.36 per share until January 17, 2024.

On February 12, 2019, the Company closed a private placement of 540,000 units at CDN\$0.25 per unit for gross proceeds of CDN\$135,000. Each unit consists of one share of common stock of the Company and one transferable common stock purchase warrant. Each full warrant is exercisable at a price of CDN\$0.36 per share until February 12, 2024.

On February 21, 2019, the Company closed a private placement of 2,123,188 units at CDN\$0.25 per unit for gross proceeds of CDN\$530,797. Each unit consists of one share of common stock of the Company and one transferable common stock purchase warrant. Each full warrant is exercisable at a price of CDN\$0.36 per share until February 21, 2024. The Company incurred issuance costs of CDN\$49,679 and issued a total of 125,264 compensation warrants. The compensation warrants are exercisable into units (“Broker Units”) at \$0.25 per unit until February 21, 2024. Each Broker Unit consists of one common share and one common stock purchase warrant (“Agent’s Warrant”). Each Agent’s Warrant is exercisable at \$0.36 per share until February 21, 2024.

On April 2, 2019, the Company closed a private placement of 3,017,132 units at CDN\$0.25 per unit for gross proceeds of CDN\$754,283. Each unit consists of one share of common stock of the Company and one transferable common stock purchase warrant. Each full warrant is exercisable at a price of CDN\$0.36 per share until April 2, 2024.

On May 6, 2019, the Company closed a private placement of 1,250,000 units at CDN\$0.25 per unit for gross proceeds of CDN\$312,500. Each unit consists of one share of common stock of the Company and one transferable common stock purchase warrant. Each full warrant is exercisable at a price of CDN\$0.36 per share until May 6, 2024. The Company incurred issuance costs of CDN\$18,750 and issued a total of 75,000 compensation warrants. The compensation warrants are exercisable into units (“Broker Units”) at \$0.25 per unit until May 6, 2024. Each Broker Unit consists of one share of common stock and one common stock purchase warrant (“Agent’s Warrant”). Each Agent’s Warrant is exercisable at \$0.36 per share until May 6, 2024.

## **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no off-balance sheet arrangements that would require disclosure.

## **MANAGEMENT AND RELATED PARTY TRANSACTIONS**

The Company’s Board of Directors consists of Peter Bakema, Paul Blunden, and Dallas Hack. Mr. Peter Bakema acts as President and Chief Executive Officer, Mr. Tom Harris acts as Chief Financial Officer and Mr. Anthony Robinson acts as Chief Operating

Officer. Mr. Peter Bakema is also the founder, Chief Executive Officer, Chairman of the Board of Directors, and a significant shareholder of CVR Global Inc., and Mr. Paul Blunden is also a director and significant shareholder of CVR Global Inc.

- a) During the year ended December 31, 2018, the Company incurred \$593,333 (2017 - \$185,084) in research and development costs related to key management compensation paid to the Chief Executive Officer (“CEO”) of the Company, Chief Operating Officer (“COO”) of the Company, a director of the Company and companies controlled by the CEO of the Company, the COO of the Company and a director of the Company. Prior to the termination of the joint operation on October 31, 2018, the key management compensation consists of 50% of the fees to each of the parties above, with the remaining 50% being incurred by CVR Global Inc. and included in the write-off of advance from CVR Global, Inc. Effective November 1, 2018, the key management compensation consists 100% of the fees to each of the parties above, which is included in research and development costs.
- b) During the year ended December 31, 2018, the Company incurred \$20,454 (CDN\$26,000) (2017 - \$65,685 (CDN\$85,150)) in consulting fees to the former CFO of the Company. As at December 31, 2018, the Company owed \$9,236 (CDN\$12,600) (2017 - \$5,711 (CDN\$7,180)) to the former CFO of the Company. The amount is unsecured, non-interest bearing and due on demand.
- c) During the year ended December 31, 2018, the Company incurred \$182,417 (2017 - \$nil) in consulting fees to the CFO of the Company. As at December 31, 2018, the Company owed \$119,478 (2017 - \$nil) to the CFO of the Company. The amount is unsecured, non-interest bearing and due on demand.
- d) During the year ended December 31, 2018, the Company incurred \$nil (2017 - \$22,371 (CDN\$29,000)) in consulting fees to a company controlled by a former director of the Company. As at December 31, 2018, the Company owed \$nil (2017 - \$12,726 (CDN\$16,000)) to the former director of the Company. The amount is unsecured, non-interest bearing and due on demand.
- e) During the year ended December 31, 2018, the Company incurred \$nil (2017 - \$21,214 (CDN\$27,500)) in consulting fees and \$nil (2017 - \$70,881 (CDN\$91,886)) in share-based compensation to a company controlled by a former director of the Company. As at December 31, 2018, the Company owed \$5,498 (CDN\$7,500) (2017 - \$5,966 (CDN\$7,500)) to the former director of the Company. The amount is unsecured, non-interest bearing and due on demand.
- f) During the year ended December 31, 2018, the Company incurred a total of \$32,763 (CDN\$42,000) (2017 - \$7,714 (CDN\$10,000)) in consulting fees and \$93,333 (2017 - \$nil) in director fees to four directors of the Company. As at December 31, 2018, the Company owed a total of \$101,402 (2017 - \$nil) to the four directors of the Company. The amounts are unsecured, non-interest bearing and due on demand.
- g) During the year ended December 31, 2018, the Company incurred consulting fees of \$158,005 (2017 - \$nil) to the Executive Vice President (“Executive VP”) of the Company. At December 31, 2018, the Company owed \$52,533 (2017 - \$nil) to the Executive VP of the Company, which is included in accounts payable. The amount is unsecured, non-interest bearing and due on demand.

- h) During the year ended December 31, 2018, the Company incurred interest expense of \$30,000 (2017 – \$nil) to the spouse of a director of the Company pursuant to a promissory note payable.
- i) As at December 31, 2018, the Company owed a shareholder of the Company \$nil (2017 - \$18,464) and \$nil (2017 – \$5,568 (CDN\$7,000)) for advances.
- j) As at December 31, 2018, the Company owed a shareholder of the Company \$31,000 (2017 - \$31,000) for advances.
- k) As at December 31, 2018, the Company owed CVR Global a total of \$437,461 (2017 – \$nil) for research and development expenses pursuant to the Commercialization Agreement.

### ***Loan Receivable from CVR Global, Inc.***

On August 1, 2017, CVR Global entered into a Commercial Sub-lease Agreement (the “Agreement”) with LJ Trader, Inc., a company owned by the CEO of the Company, which leased the property from the owner. The property being leased (the “Property”) is the head office of the Company and is also the personal residence of the CEO and is owned by LJ Trader, Inc, which is owned by the CEO. The property also is used by CVR Global corporate meetings. The CEO individually holds an option to purchase the property that expires on November 29, 2019.

As the Company and CVR Global did not have a formal office in the immediate area, it was determined that the Property was ideal for local independent contractors, who perform daily management, administrative and research and development activities and services on behalf of CVR Global, given the Property was easily accessible for these independent contractors. The Property required leasehold improvements to make it suitable for larger meetings and for independent contractors and Board Members who meet and also stay overnight at the Property.

At December 31, 2018, the Company has provided a total of \$130,659 to CVR Global to fund leasehold improvements incurred by CVR Global on the Property (the “Recoverable Costs”). Pursuant to a sub-lease agreement between CVR Global and LJ Trader Inc., and an agreement between CVR Global and the Company, these costs shall be reimbursed to CVR Global in the event the CEO of the Company exercises his option to purchase the Property and the Property is subsequently sold. Furthermore, pursuant to a subsequent agreement between the Company and CVR Global dated July 30, 2019, the CVR Global shall pay to the Company an amount equal to \$130,659 (the “Loan”) within 2 business days of receipt by sale proceeds the CEO of the Company (the “Payment Date”). Management of CVR Global will be responsible for collecting the funds from the CEO of the Company. CVR Global acknowledges and agrees that if CVR Global has not repaid the Loan within 2 business days of the Payment Date, the Company has the right to deduct an amount equal to the Loan from any invoices then due or due in the future from the Company to CVR Global up to an amount equal to the Loan.

During the year ended December 31, 2018, the Company also provided a total of \$100,762 (2017 - \$28,810) to CVR Global, comprised of rent \$44,000 (2017 - \$10,000) and maintenance of \$56,762 (2017- \$18,810), related to the leased property, which have been recognized as operating expenses.

The Restructuring Agreement, effective November 1, 2018, has a clause which indicates that any and all amounts due between the Company and CVR Global will be forgiven upon completing the restructuring. However, as set forth in the above referenced agreement, management of both the Company and CVR Global have separately agreed that the costs relating to the \$130,659 in

property improvement costs will be considered separately and that these costs are not subject to the debt forgiveness clause.

## **SHARE DATA**

Authorized share capital consists of unlimited number of common shares without par value.

As at the date of this MD&A, the Company had 101,377,872 common shares issued and outstanding, and had 25,000,000 common shares in escrow pursuant to the Restructuring Agreement with CVR Global.

As at the date of this MD&A, the Company had 7,950,000 stock options and 25,866,585 warrants outstanding.

## **MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL INFORMATION**

The Company's consolidated financial statements and the other financial information included in this management report are the responsibility of the Company's management, and have been examined and approved by the Board of Directors. The consolidated financial statements were prepared by management in accordance with International Financial Reporting Standards and include certain amounts based on management's best estimates using careful judgment. The selection of accounting principles and methods is management's responsibility. Management recognizes its responsibility for conducting the Company's affairs in a manner to comply with the requirements of applicable laws and established financial standards and principles, and for maintaining proper standards of conduct in its activities.

The Board of Directors supervises the consolidated financial statements and other financial information through its audit committee, which is comprised of a majority of non-management directors.

This committee's role is to examine the consolidated financial statements and recommend that the Board of Directors approve them, to examine the internal control and information protection systems and all other matters relating to the Company's accounting and finances. In order to do so, the audit committee meets annually with the external auditors, with or without the Company's management, to review their respective audit plans and discuss the results of their examination. This committee is responsible for recommending the appointment of the external auditors or the renewal of their engagement.

## **INDUSTRY CONDITIONS AND RISKS**

The Company has identified certain risks and uncertainties that may have a material adverse effect on its business, results of operations, or financial condition. In any such case, the market price of its common shares could decline, and investors may lose all or part of their investment. Only potential investors who are experienced in high risk investments and who can afford to lose their entire investment should consider an investment in the Company.

The following list of risk factors is not exhaustive. Investors should carefully consider these and other risks, one or all of which may be material, before purchasing securities of the Company. The Company will, on occasion, make forward looking statements about its expectations, its business and industry, and operations. These forward-looking statements are made at a point in time, based



on certain assumptions. They are subject to change without notice as a result of the risks described herein and other risks. Investors or potential investors in the Company should not rely on forward-looking statements or the Company's historical operating performance as a prediction of actual results, and the Company undertakes no obligation to update forward looking information. In addition, the Company operates in a rapidly changing business, economic and regulated environment, and new potentially material risk factors emerge from time to time.

*The market may not accept the Company's products, which will adversely affect its business, financial condition, and results of operations*

The market acceptance of the Company's products will depend upon the medical community accepting the products as clinically useful, reliable, accurate, and cost-effective compared to existing and future products or procedures. Market acceptance will also depend on the Company's ability to demonstrate the clinical efficacy and safety of the Company's products and future products. Failure of these new products to achieve significant market share could have material adverse effects on the Company's long-term business, financial condition, and results of operation.

*The Company's success depends on the successful commercialization of its technology.*

The successful commercialization of the Company's technology is crucial for its success. Even if the Company's technology is shown to be less costly and more effective, the Company may face unforeseen difficulties in manufacturing and marketing the Company's products. These difficulties may only become apparent upon scaling up manufacturing to commercial levels. In addition, there is no guarantee that market acceptance will come upon the successful manufacturing and sale of any product. If the Company's technology and products do not result in commercially successful products, the Company's business could be adversely affected.

### *Regulatory Approvals*

Medical devices are subject to regulatory clearances within individual markets and jurisdictions. As such, they are evaluated for compliance with established consensus standards. When a new technology is involved, in order to get USA clearance through the FDA approval process. With a non-invasive / non-emitting medical device that possesses a lower level of risk typically the 510(k) process would be followed in which a manufacturer must identify an existing "predicate" device from which to compare the new technology. If no clear predicate device is identified then the submission must be conducted under the De Novo submission process, or the PMA process for higher risk devices. Clearance in the USA is potentially the most important to obtain and maintain due to the size of that market and its importance in terms of practice. There is no guarantee that the device will get FDA clearance / approval.

*Inability to complete future research and development and engineering projects in a timely manner could have a material adverse effect of our results of operations, financial condition and cash flows.*

If research and development projects are not completed in a timely fashion, the Company could experience:

- substantial additional cost to obtain a marketable product;

- additional competition resulting from competitors in the surveillance and facial recognition market; and
- delay in obtaining future inflow of cash from financing or partnership activities.

*The Company could face intense competition, which could result in lower revenues and higher research and development expenditures and could adversely affect the results of operations.*

Unless the Company keeps pace with changing technologies, the Company could lose existing customers and fail to win new customers. In order to compete effectively in providing medical diagnostic solutions for healthcare providers, the Company must continually design, develop and market new and enhanced technologies. The future success of the Company will depend, in part, upon its ability to address the changing and sophisticated needs of the marketplace. Medical diagnostic solution technologies are difficult to achieve widespread commercial acceptance and adoption.

The market for medical diagnostic solutions of the Company is still developing and if the industry adopts test criteria that are different from internal test criteria of the Company, our competitive position would be negatively affected. Our plan to pursue sales in international markets may be limited by risks related to conditions in such markets.

*Certain laws and governmental regulations which could affect international distribution and applications.*

The medical diagnostic solutions may be regulated by regionally valid legislation, including health legislation and regulations concerning use and adoption of the Patents.

*If the Company is not able to adequately protect the intellectual property, then the Company may not be able to compete effectively and may not be profitable.*

Commercial success may depend, in part, on obtaining and maintaining patent protection, trade secret protection and regulatory protection of our technologies and product candidates as well as successfully defending third-party challenges to such technologies and candidates. The Company will be able to protect our technologies and product candidates from use by third parties only to the extent that valid and enforceable patents, trade secrets or regulatory protection cover them and we have exclusive rights to use them. The ability of licensors, collaborators and suppliers of the Company to maintain their patent rights against third-party challenges to their validity, scope or enforceability will also play an important role in determining our future.

The copyright and patent positions of software and technology related companies can be highly uncertain and involve complex legal and factual questions that include unresolved principles and issues. No consistent policy regarding the breadth of claims allowed regarding such companies' patents has emerged to date in the Canada, and the patent situation outside Canada is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in Canada or other countries may diminish the value of the Patents. Accordingly, the Company cannot predict with any certainty the range of claims that may be allowed or enforced concerning patents of the Company.

The Company may also rely on trade secrets to protect our technologies, especially where the Company does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While the Company seeks to protect confidential information, in part, through confidentiality agreements with our consultants and scientific and other advisors, they may unintentionally or willfully disclose our information to competitors. Enforcing a claim against a third party related to the illegal acquisition and use of trade secrets can be expensive and time consuming, and the outcome is often unpredictable. If we are not able to maintain patent or trade secret protection on our technologies and product candidates, then we may not be able to exclude competitors from developing or marketing competing products, and we may not be able to operate profitably.

*If the Company is the subject of an intellectual property infringement claim, the cost of participating in any litigation could cause the Company to go out of business.*

There has been, and the Company believes that there will continue to be, significant litigation and demands for licenses in the medical diagnostic industry regarding patent and other intellectual property rights. Although the Company anticipates having a valid defense to any allegation that the Patents infringe the valid and enforceable intellectual property rights of any third parties, the Company cannot be certain that a third party will not challenge the position of the Company in the future. Other parties may own patent rights that the Company might infringe with the Patents or other activities, and our competitors or other patent holders may assert that our products and the methods that the Company employs are covered by their patents. These parties could bring claims against the Company that would cause the Company to incur substantial litigation expenses and, if successful, may require the Company to pay substantial damages. Some of the potential competitors may be better able to sustain the costs of complex patent litigation, and depending on the circumstances, the Company could be forced to stop or delay research, development, manufacturing or sales activities. Any of these costs could cause the Company to go out of business.

*The Patents may become obsolete and unmarketable if the Company is unable to respond adequately to rapidly changing technology and customer demands.*

Medical diagnostic industry is characterized by rapid changes in technology and customer demands. As a result, products and software of the Company may quickly become obsolete and unmarketable. The Company's future success will depend on the ability to adapt to technological advances, anticipate customer demands, develop new products and enhance current products on a timely and cost-effective basis. Further, products and software of the Company must remain competitive with those of other companies with substantially greater resources. The Company may experience technical or other difficulties that could delay or prevent the development, introduction or marketing of new products and software or enhanced versions of existing products. Also, the Company may not be able to adapt new or enhanced services to emerging industry standards, and new products and software of the Company may not be favorably received.

*Failure to achieve and maintain the high manufacturing standards that the Company's products require may seriously harm its business.*

The Company's products require precise and high-quality manufacturing. Achieving precision and quality control requires skill and diligence by the Company's personnel or manufacturers, as well as its vendors. Any failure on the Company's, or its manufacturer's, part to achieve and maintain

these high manufacturing standards, including the incidence of manufacturing errors, design defects or component failures, could conceivably result in physical injury, harm or the death of end users of the Company's products, product recalls or withdrawals, delays or failures in product testing or delivery, cost overruns or other problems that could seriously harm the Company's business. Despite the Company's anticipated high manufacturing standards, the Company cannot completely eliminate the risk of errors, defects or failures. If the Company is unable to eliminate the risk of errors, defects or failures, its business and results of operations may be negatively affected.

*The Company is dependent on its suppliers and manufacturers to meet existing regulations.*

Future suppliers and manufacturers could be subject to heavy government regulation. This may include United States Food and Drug Administration (the "USFDA") Quality System Regulation compliance in the operation of their facilities, products, and manufacturing processes. Any adverse action by the USFDA against the Company's suppliers or manufacturers could delay supply or manufacture of component products required to be integrated or sold with the Company's products. There are no assurances that the Company will be successful in locating an alternative supplier or manufacturer to meet product shipment or launch deadlines. As a result, the Company's sales, contractual commitments, and financial forecasts may be significantly affected by any such delays.

## **RECENT ACCOUNTING PRONOUNCEMENTS**

Certain pronouncements were issued by the IASB or the IFRS Interpretations Committee that are mandatory for annual periods beginning after January 1, 2019, or later periods.

The following new IFRSs that have not been early adopted in these consolidated financial statements will not have a material effect on the Company's future results and financial position:

- i) IFRS 16, *Leases* (New; to replace IAS 17, IFRIC 4, SIC-15 and SIC-27).

Other accounting standards or amendments to existing accounting standards that have been issued but have future effective dates are either not applicable or are not expected to have a significant impact on the Company's consolidated financial statements.

## **CRITICAL ACCOUNTING ESTIMATES**

The consolidated financial statements of the Company for year ended December 31, 2018, were prepared in accordance with IFRS applicable to a going concern which assumes that the Company will realize its assets and discharge its liabilities and meet its future obligations in the normal course of business. Accordingly, the consolidated financial statements do not include any adjustments for the recoverability and reclassification of recorded assets, or the amounts or classification of liabilities, that might be necessary should the Company be unable to continue as a going concern. Such adjustments could be material. However, there is significant doubt as to the appropriateness of the going concern presumption. There is no assurance that the Company's funding initiatives will continue to be successful.

### *Share-based Payment Transactions*

The Company measures the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date at which they are granted. Estimating fair value for

share-based payment transactions requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. The estimate also requires determining the most appropriate inputs to the valuation model including the expected life of the stock option, volatility and dividend yield and making assumptions about them.

## **INVESTOR RELATIONS**

On September 27, 2016, the Company entered into a consulting agreement with a third party for the provision of investor relation services. The consultant will initiate and maintain contact with the financial community, shareholders, investors and other stakeholders for the purpose of increasing awareness of CVR Medical and its activities. The agreement is for an ongoing basis and may be terminated by either party by 30 days of written notice and is subject to approval from the TSX Venture Exchange.

## **ADDITIONAL INFORMATION**

Additional information relating to CVR Medical is located at [www.sedar.com](http://www.sedar.com).