



CVR Medical Corp.

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Ticker (Exchange)	CVM (TSX.V)
Recent Price (07/23/2018)	C\$0.355
52-week Range	C\$0.28 - \$0.50
Shares Outstanding*	70.9 million
Market Capitalization	C\$25.2 million
Average 3-month Volume	64,833
Insider Ownership +>5%	~18%
Institutional Ownership	~10%
EPS (Year ended 12/31/2017)	(C\$0.15)
Employees	~20*

*including contractors

CVM (TSX.V) One-year Stock Chart



CAROTID STENOTIC SCAN (CSS) DEVICE



Earlier detection for quicker treatment of stroke.

Company Description

CVR Medical Corp. (“CVR Medical” or “the Company”) is a medical technology company developing and commercializing a revolutionary device to assess **carotid arterial†** health. The technology is intended to quickly and cost-effectively identify patients with arterial narrowing, which puts them at risk for **ischemic stroke**, in order to enable early intervention. Performed in a primary care physician’s office, the Company’s **Carotid Stenotic Scan (CSS)** uses low frequency sound wave analysis to non-invasively detect and measure carotid arterial **stenosis** (narrowing of the blood vessels in the neck that carries blood from the heart to the brain) or **occlusion** (blockage)—which is the leading risk factor for **stroke**. The CSS, which can be performed within two minutes by a medical technician in the office, costs less than invasive diagnostics, such as **duplex Doppler ultrasound (DUS)**, **magnetic resonance angiography (MRA)**, **computed tomography angiography (CTA)**, or **cerebral angiogram**, and provides results at the point of care. Stroke is a very serious medical condition that requires immediate emergency care as it can cause lasting brain damage, long-term disability, or death. Primary care physicians currently lack a cost-effective tool to initially assess their patients’ arterial health. The CSS device is undergoing final phase trials at several world-renowned medical institutions and is positioned for imminent U.S. FDA submission, expected to be followed by market clearance and launch—targeted for 1H 2019.

Key Points

- Stroke is the fifth leading cause of death in the U.S., resulting in one out of 20 adult deaths, at a cost of roughly \$34 billion per year. Many of these deaths could be preventable. While cardiac disease is the primary cause of death, stroke is the leading cause of long-term disability (50% of patients are permanently impaired).
- The Company announced in January 2018 the start of clinical trials at the Henry Ford Hospital in Detroit. Additionally, Thomas Jefferson University Hospital in Philadelphia is expected to begin pivotal trials following promising preliminary results of its ongoing ENTICES Study, evaluating CSS against current ultrasound technologies. Furthermore, in February 2018, the Company announced Internal Review Board (IRB) approval by the Cleveland Clinic, sanctioning CVR Medical to conduct clinical trials using the CSS device.
- CVR Medical has a contract with Canon U.S.A. to build and manufacture its CSS device, where Canon will manufacture, assemble, handle all logistics (including tech support), and ‘white glove’ deliver the CSS to the doctor’s office. Canon brings significant value to the Company as it has a dedicated space with the ability to scale production as CVR Medical transitions into a full scale medical device sales and marketing company.
- CVR Medical’s intellectual property (IP) portfolio includes one issued patent, 13 pending, and more than 20 under process, with significant IP surrounding its CSS, including 4K encrypted proprietary software.
- The Company’s executive team consists of veterans from the medical device industry with business acumen from key areas in healthcare.



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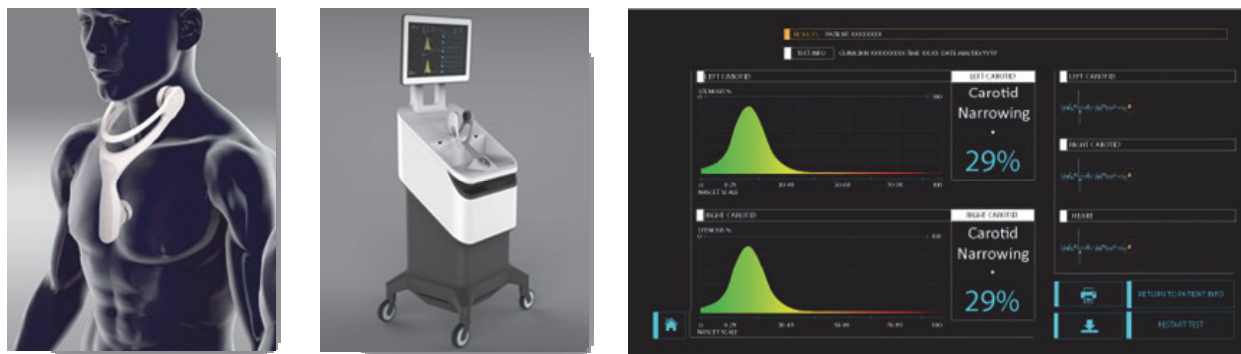
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Note: All amounts cited in this section are in U.S. dollars unless noted otherwise.

Executive Overview

CVR Medical Corp. (“CVR Medical” or “the Company”) is a medical technology company dedicated to developing and commercializing a revolutionary device within the healthcare sector to assess carotid arterial health in order to quickly and cost-effectively identify patients at risk for stroke and enable early intervention. The Company’s Carotid Stenotic Scan (CSS) can be easily performed within several minutes by a medical technician in the primary care physician’s office, requires only a small footprint, and has a price per scan that is significantly less as an initial screening tool versus the resource and cost requirements associated with other more invasive diagnostic technologies. Using low frequency sound wave analysis, the CSS can non-invasively detect and measure carotid arterial stenosis or occlusion quickly, as these are leading risk factors for stroke. The Company has focused on making the CSS both efficient and hassle free for all end users, with a simple login screen, easy to order disposables, and wireless technology. Figure 1 provides a rendering of the CSS and the special sensors used with the device, as well as screen that displays results of a scan.

Figure 1
THE CAROTID STENOTIC SCAN (CSS) DEVICE



Source: CVR Medical Corp.

Currently used diagnostics to assess arterial health include duplex Doppler ultrasound (DUS), magnetic resonance angiography (MRA), computed tomography angiography (CTA), and cerebral angiogram, among others, which are costly, require a large space for the equipment, need licensed personnel to operate, and take upwards of 30 to 60 minutes to conduct, with the more common of these diagnostics highlighted in Figure 2. With an anticipated market price of \$49,000 per device, the CSS is significantly more economical than alternative technologies, which can cost as much as \$2.5 million per machine.

Figure 2
CURRENT DIAGNOSTICS LANDSCAPE AND POTENTIAL NEW SOLUTION

	Carotid Doppler Ultrasound (DUS)	Magnetic Resonance Angiography (MRA)	Computed Tomography Angiography (CTA)	Carotid Stenotic Scan (CSS)
Cost	\$250,000	\$1 mm - \$2.5 mm	\$1 mm - \$2.5 mm	\$49,000
No certified tech required	X	X	X	✓
Fee	\$\$\$	\$\$\$\$	\$\$\$\$	\$
Reimbursement	\$180-\$400	\$3,000	\$500 - \$1,500	\$105*
Non-emitting	X	X	X	✓
Non-invasive	✓	✓	✓	✓
Accurate and repeatable	X	X	X	✓
Time requirement	30-60 minutes	>60 minutes	30-60 minutes	2 minutes

*estimate

Source: CVR Medical Corp.



The Company's CSS is in final phase pivotal clinical trials, which is intended be used to submit to the U.S. Food and Drug Administration (FDA) in order to receive market clearance, targeted for 1H 2019. The Company is initially focused on selling its device into U.S. markets. As well, CVR Medical has recently announced distribution partnerships to enter additional markets in China and South Korea. The Company's CSS is intended to be classified as a low-risk non-emitting and non-invasive **Class II (FDA) product** in the U.S.—benefits that are expected to lead to an added advantage upon commercialization.

A very serious medical condition, stroke requires immediate emergency care as it can cause lasting brain damage, long-term disability, or death. There is currently no cost effective and universally accepted way to assess the health of carotid arteries (stroke risk) by a primary healthcare provider. The CSS device is designed to diagnose cardiovascular health in patients from a primary care physician's office to be able to ensure proper medical treatment at an early stage.

Carotid Artery Disease

Carotid artery disease is a disease in which plaque builds up inside the carotid arteries and can cause a stroke, also called a "brain attack." A stroke occurs when blood flow to a person's brain is cut off. There are two common carotid arteries, one on each side of the neck, each of which divide into internal and external carotid arteries. The internal carotid arteries supply oxygen-rich blood to a person's brain; the external carotid arteries supply oxygen-rich blood to the face, scalp, and neck. A stroke occurs when the flow of oxygen-rich blood to a portion of the brain is blocked, at which point, brain cells begin to die after only a few minutes. Sudden bleeding in the brain can also cause a stroke if it damages brain cells. If brain cells are damaged or die from a stroke, symptoms occur in the parts of the body that these brain cells control, and can include sudden weakness; paralysis or numbness of the face, arms, or legs; trouble speaking or understanding speech; and difficulty seeing.

Similar to a stroke, a **transient ischemic attack (TIA)** or mini-stroke occurs if blood flow to a portion of the brain is blocked, often by a blood clot, for a short period of time (however the damage to the brain cells is not permanent). While not a full-blown stroke, a TIA greatly increases stroke risk. Symptoms of TIAs include weakness on one side of the body, vision problems, and slurred speech, though these symptoms are transient and often resolve within 24 hours. Physician diagnosis of a TIA is critical in order to determine its cause and to take necessary measures to prevent another one from happening.

In either situation, both strokes and TIAs require emergency care. According to the U.S. Centers for Disease Control and Prevention (CDC), 93% of respondents in one survey recognized sudden numbness on one side as a symptom of stroke, however only 38% of these respondents were aware of all major symptoms of a stroke and knew to call 911. Recognizing the signs and symptoms of a stroke is critical since patients who arrive at the emergency room within three hours of their first symptoms often have fewer disabilities three months after a stroke than those whose care was delayed.

Statistics

Every year, more than 795,000 people in the U.S. experience a stroke and 140,000 of these individuals die (one in 20 deaths), making it the fifth leading cause of death. Every 40 seconds, someone has a stroke and every four minutes someone dies from one. The leading cause of death in the U.S. is cardiovascular disease, in which roughly 735,000 American's suffer a heart attack every year, resulting in 610,000 deaths (one in every four deaths). While the incidence of strokes and heart attacks is roughly the same, stroke is the leading cause of disability; 50% of victims end up with lifelong disability and 12% prove fatal, whereas 83% of heart attack victims die (Source: CDC). Stroke costs the U.S. an estimated \$34 billion each year and an estimated \$72 billion worldwide. This total includes the cost of healthcare services, medicines to treat stroke, and missed days of work. Risk of stroke increases with age, however, it can—and often does—occur at any age. In 2009, 34% of people hospitalized for stroke were under age 65.

The Potential Dilemma with Current Diagnostics

Today, in order to make a diagnosis as to whether a patient is experiencing a stroke, a physician must learn as much as possible about a patient's symptoms, current and previous medical problems, current medications, and family history. As well, the physician performs a physical exam to listen to the carotid artery with a stethoscope in order to attempt to detect a swishing noise called a **bruit**, as this noise may signal turbulent blood flow caused by **atherosclerosis** (however, it is long disputed whether bruits can actually predict stenosis in **symptomatic** patients). Based on this, the patient may be sent on for further diagnostic tests to detect narrowing of the carotid arteries. Currently, carotid stenosis can be diagnosed by either a duplex Doppler ultrasound (DUS), computed tomography angiogram (CTA) of the neck, magnetic resonance angiography (MRA), or cerebral angiogram, or other diagnostics with the most common described in brief below and profiled in the accompanying section, noting that MRA dominates the diagnostic segment of stroke diagnostics. Imaging also can reveal evidence of multiple small strokes.

- *Duplex Doppler Ultrasound (DUS)*. A duplex Doppler ultrasound (**sonography**) of the neck is the most common test to diagnose carotid artery disease. This painless, harmless test uses sound waves to create pictures of the insides of the carotid arteries to show whether plaque has narrowed the carotid arteries, and if it has, how narrow they are. A standard carotid ultrasound shows the structure of the carotid arteries; whereas a Doppler carotid ultrasound shows how blood moves through the carotid arteries. The test takes approximately 30 to 60 minutes, and is done in an ultrasound lab.
- *Magnetic Resonance Angiography (MRA)*. MRA employs a large magnet and radio waves to take pictures of the carotid arteries, where these pictures can be viewed on a computer screen. Contrast dye may be given to the patient to highlight the carotid arteries on the pictures. MRA is most often used to examine vessels in the brain, neck, kidneys, and legs. The test takes under an hour and is done in either a lab or hospital setting.
- *Computed Tomography Angiography (CTA)*. CTA takes X-ray pictures of the body from many angles and a computer then combines the pictures into two- and three-dimensional images. As with other tests, dye may be injected into the patient to highlight the carotid arteries on the pictures.
- *Cerebral angiogram*. This diagnostic test uses an X-ray to find blockages or other abnormalities in the blood vessels of the head and neck. A patient is injected with contrast medium to help create a clean picture of the blood vessels on the X-ray.

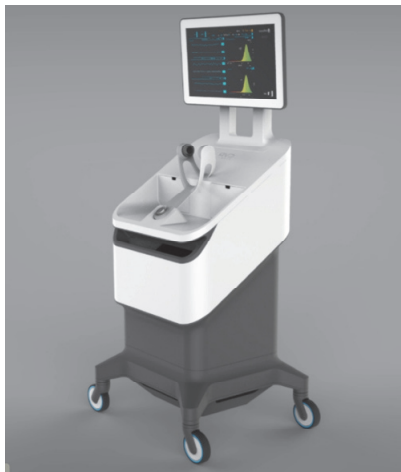
Primary care doctors currently do not have the tools necessary to diagnose a stroke during a regular patient office exam as the equipment typically required to do so—DUS, CTA, MRA, etc.—require a large space and licensed personnel to operate. Therefore, a patient's arterial health is only checked when a patient presents with clear signs and symptoms of a stroke (such as being able to hear a bruit) and/or is symptomatic. However, when a patient has only one symptom, while it could be a stroke, it could also be anything from a headache to something else; in this case, the patient is said to be **asymptomatic**, and the decision of to how to treat this patient must be made. If the primary makes the decision for further testing, the patient is sent to a lab for diagnostic testing, followed by the lab recommending that the patient see a cardiovascular specialist who works with that lab. At that point, the primary care physician is likely to lose that patient as he/she becomes a patient of the cardiovascular specialist patient (noting many patients then use the cardiologist as their primary care doctor).

The next issue is that since the primary care physician currently does not have the technology available in the office to diagnose Carotid Artery Disease, when the patient is sent off for testing, data may come back indicating under 50% or over 50% stenosis. The problem is when a patient presents with several indicators and is above 50% stenosis, the patient must be sent on to a cardiologist despite the possibility that there may not be a problem. In a patient who is below 50% stenosis, this may either be a false negative or false positive situation.

Additionally, in a large percentage of states, primary care doctors may not get reimbursement for a diagnostic procedure. In order to receive reimbursement in a primary care office, it must be an **Intersocietal Accreditation Commission (IAC)** imaging facility or hospital specific to vascular testing. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide. It requires a very highly skilled certified technician to have IAC accreditation, which is the reason most primary care physicians are not part of the IAC program. ***CVR Medical's technology changes this situation, bringing this important diagnostic test into the primary care physician's office to quickly and cost effectively screen patients for carotid arterial disease.***

CVR Medical's CSS Solution

Figure 3
THE CAROTID STENOTIC SCAN (CSS) DEVICE



Source: CVR Medical Corp.

The CSS technology (Figure 3) has been developed to almost immediately detect and diagnose a problem at the point of care. Having demonstrated the ability to be accurate and repeatable, the CSS is able to provide precise information to determine whether a patient goes on to see a cardiovascular specialist for further testing or is not a candidate at that point for a stroke and is sent home. Importantly, the Company is currently not able to state that the device can determine an individuals' *actual* risk for stroke since, under regulatory guidelines, this cannot be stated unless it can be proven.

The CSS device has demonstrated to not only be a potential lifesaver for the patient but also becomes a profit center for the primary care physician and a money saver for the payor (where the payors will significantly reduce their costs for running unnecessary laboratory diagnostic testing). These reduced costs include reduced false positives and fewer patients sent for unnecessary imaging. For payors such as insurance companies, Medicare, Medicaid, U.S. Department of Veterans Affairs (VA), and Federal, State, and Local Governments, these organizations would realize significant cost savings as patients can be screened and potentially avoid being sent for costly laboratory diagnostic tests. The CSS can also be used in patients as young as 20 to establish a baseline, which is important since while the risk of stroke increases with age, it can and often does occur at any age.

Science Behind the CSS Technology

The CSS works by analyzing the sound waves produced by the blood flowing through the carotid arteries. Developed in cooperation with the Army Research Lab under a Cooperative Research and Development Agreement, proprietary sensors provide low frequency acoustic coupling from the carotid arteries to the CSS. When blood normally flows within an artery or a vein, it creates sound waves at a particular frequency. Narrowing of the blood vessel, due to plaque buildup or the presence of a blockage, creates a change in the blood pressure and the frequency of the sound waves produced by the blood flow. These changes can be analyzed by the device to assess the carotid arterial health of the patient.

FDA Status

The Company announced on May 9, 2018 the 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. Attendees of the meeting included CVR Medical management, regulatory consultant's Duval & Associates (www.duvalfdalaw.com), and key reviewers from the FDA. The purpose of the meeting was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing. Importantly, CVR Medical has retained Duval & Associates and JD Lymons (<http://jdlymon.com>) as counsel guiding the Company through both the FDA as well as CMS. Based on prior communication with the FDA and input provided by key regulatory advisors, CVR Medical 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.

Worth noting is that a **Premarket Approval (PMA)** is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of medical devices; a 510(K), is for when there is a comparator of the Company's device to another device. There is no comparator to CVR Medical's device, however, as the Company understands from its meeting with the FDA, the Organization has made a change such that if the device produces the same outcome as another device, the FDA will accept those as predicate.

The FDA has since come out with the **de novo application**. A *de novo* application is something in between a PMA and a 510(K) that is sent by the medical device sponsor to the FDA. If granted, *de novo* establishes a new "device type" along with classification, regulation, necessary controls, and product code, where the device is eligible to serve as a predicate for new medical devices when appropriate. The risk to the *de novo* is that it requires greater amounts of data, and while it does not explicitly require more time, the increase in data could cause an increase in the necessary timeframe.

The Company's CSS device is currently in the final clinical phase of development, with CVR Medical preparing for submission to the FDA. This is expected to be followed by market clearance and launch, which the Company anticipates could happen in early 1H 2019.

Thomas Jefferson University Hospital

CVR Medical announced in June 2017 that Thomas Jefferson University Hospital (Jefferson Clinical Research Institute) issued an initial trial report summarizing the clinical trial progress of the CSS under the supervision of principal investigator, Dr. David Whellan, MD, MHS, FACC, FAHA. The ENTICES (Evaluation of a Novel Technique to Investigate CAS piezo-Electric Sensors) Study is assessing CSS against current ultrasound technology. This study is enrolling at a robust pace with data on over 125 patients. A major factor in the successful enrollment, which began in January 2017, has been the ease at which CSS data can be acquired, allowing participants to have test studies performed quickly.

As the first study evaluating the CSS technology, the overall objectives are to determine that the CSS can accurately detect significant carotid artery stenosis. A secondary objective is to relate changes in CSS signal to different degrees of stenosis. "Proof of concept" is obtained if the device correlates strongly with the established classification of atherosclerotic carotid disease derived from various imaging modalities, including MRA, CTA, conventional angiography, or carotid ultrasound (described on pages 21-23). The CSS device is now in pivotal trials, which is intended to be used to support FDA submission for market clearance.

Henry Ford Hospital

CVR Medical announced on January 23, 2018 the commencement of clinical data acquisition by the CSS device at Michigan's Henry Ford Hospital. There is currently one wireless CSS device fully deployed within the Henry Ford system, with two additional devices slated for implementation in coming weeks. This clinical trial plays a crucial role in accelerating clinical substantiation for the CSS device and shortening the timeline. The team at Henry Ford possesses the expertise and experience necessary to successfully validate the effectiveness of the CSS device, having been recognized for its excellence in the area of cardiology and cardiovascular surgery. The trial will be overseen by Primary Investigator, Dr. Judith Lin, Senior Staff Surgeon and Medical Director of Henry Ford's Clinical Vascular Laboratory.

Cleveland Clinic Clinical Trials

In February 2018, the Company announced Internal Review Board (IRB) approval by the Cleveland Clinic, sanctioning CVR Medical to conduct clinical trials using the CSS device. The trial is to 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 U.S. 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 largest and most respected hospitals in the country.



Manufacturing Contract with Canon U.S.A.

CVR Medical is transitioning from a research company—undergoing clinical trials—into a full scale medical device sales and marketing company. The Company currently has a contract with Canon U.S.A. to build and manufacture its CSS devices, where Canon will completely house the product and ‘white glove’ deliver it to the doctor’s office subsequent to its sale. CVR Medical could gain a significant lead out of the box given the relationship with Canon and the fact that they have invested the time to ensure the quality of the product and its related technology. Physicians are aware of Canon and its reputation for not only delivering a quality product but also for providing any technical support when needed. Furthermore, Canon provides the Company with the ability to scale unit production.

In early January 2018, CVR Medical announced the signing of a manufacturing agreement with Canon Virginia, Inc. (CVI), a manufacturing, engineering, and technical operation for Canon and a wholly-owned subsidiary of Canon U.S.A. This agreement finalizes Canon Virginia’s status as primary manufacturer, assembler, and logistical authority for CVR Medical’s CSS device. Canon’s extensive in-house capabilities and supply-chain efficiencies could translate into millions in short-term production and logistical cost savings for CVR Medical.

Potential Expansion into International Markets

The Company is expanding into two international markets, with specifics recently announced for both China and South Korea (further described on page 35). Based on these agreements, CVR Medical expects that there could be additional agreements forthcoming as the Company’s CSS device prepares to reach the market, with upwards of a dozen agreements in process. Of note is that China and India are the most populated countries in this Asian-Pacific region, with China being the second largest economy and home to the world’s largest population—with close to 1.38 billion people.

Company Background

The Company’s predecessor, Big Bar Resources Corporation, became a medical technology company after forming a joint venture with CVR Global, Inc., (“CVR Global”) in September 2016 and changing its name to CVR Medical Corp. During this time, CVR Medical purchased the patents to CSS, which was developed by CVR Global. In order to commercialize the device, CVR Medical and CVR Global entered into an equal part equity joint venture, where under the arrangement, CVR Medical would offer patents, working capital, and global market rights. CVR Global would provide additional patents, management know-how, and intellectual property of the device and market expertise. CVR Global currently owns the rights to all of the medical applications, with the exception of the carotid arterial application, where CVR Medical owns these rights (of which there are several). CVR Medical currently owns two patents and all the intellectual property related to the carotid arterial system.

On May 29 2018, CVR Medical announced the intention to acquire 100% of the “Carotid Stenotic Scan (CSS)”. The deal has been approved by both Company’s Boards of Directors and is now subject to the approval of CVR Medical’s shareholder as well as receiving approval (inclusive of all proposed share issuances) from the TSX.V. For CVR Medical and CVR Global, the potential move is one of mutual benefit. Upon consultation with bankers, attorneys, and stakeholders, both companies recognize that this conventional milestone driven equity distribution and royalty structure significantly strengthens the business model of CVR Medical ahead of the release of its CSS device. The move from the joint venture partnership (which has served both companies effectively to this point) to this next structural phase, is believed to be a signal of confidence that CVR Medical is in position to successfully control the finalization of development and transition into marketing and sales of the CSS. Greater details on the structure of this deal are provided on page 38.

Company Leadership

Executive Management

CVR Medical’s management team is vital to developing and commercializing the CSS device. Key members of the Company’s management team and advisory and Board are highlighted in Figure 4 and profiled below.

Figure 4
MANAGEMENT AND ADVISORY STAFF

Peter Bakema	Chief Executive Officer (CEO) and Chairman of the Board
Wayne Hellman	Vice Chairman
Tony Robinson	Chief Operations Officer (COO)
Tom J. Harris	Chief Financial Officer (CFO)
Tim Knisley	Director of Finance
Alan Langston	Vice President of Sales and Marketing
Ron Birch	Board Director
Benjamin Asuncion	Board Director
Dr. Paul Blunden	Board Director, Medical Advisor
Dr. Dallas Hack	Board Director
Dr. Phillip J. Bendick, PhD	Advisory Staff

Source: CVR Medical Corp.

Peter Bakema, Chief Executive Officer (CEO) and Chairman of the Board

Mr. Bakema has a 37-year track record of successfully creating and developing businesses from the ground up. He has overseen multiple organizations with human resource development of several hundred employees and contractors. His background in business management, capitalization, and mergers and acquisitions has been combined with years of hands on leadership experience in the medical device arena, which has given him the ability to adapt quickly to a rapidly changing healthcare sector. As the Chairman and CEO of CVR Global for the past decade, Mr. Bakema is responsible for the direction of CVR Global with an emphasis on a sound business infrastructure that is capable of rapid scalability and regulatory compliance.

Wayne Hellman, Vice Chairman

Mr. Hellman’s career spans forty years, having spent 16 years in various senior management roles with General Electric, culminating with the final four years reporting directly to Jack Welch (Chairman/CEO), where he led GE’s Venture Lighting Portfolio. In 1983, Mr. Hellman founded Advanced Lighting Technologies and served as its CEO until his retirement in 2014. Advanced Lighting Technologies, a Global Leader in Specialty Chemicals, Advanced Materials, Thin Film Coatings, Metal Halide Lighting and other Specialty Lighting Products launched with first year sales of \$900,000. During his tenure, Mr. Hellman maintained consistent revenue growth and expanded global influence achieving global revenue in excess of \$250 million. With manufacturing facilities and sales offices in 9 countries, employee headcount in excess of 1,000, completing seven acquisitions and four international joint ventures in the Asian Pacific market, in 1995, Mr. Hellman led Advanced Lighting’s Initial Public Offering (IPO). In addition, he completed three secondary offerings totaling \$200 million, as well as completing a \$100 million high yield debt offering. Mr. Hellman took the Company Private in 2003 and prior to his retirement, in 2012, he led and completed an additional \$170 million High Yield Debt Offering, where a significant amount was a distribution to the company’s shareholders.



Tony Robinson, Chief Operations Officer (COO)

Mr. Robinson has directed multiple organizations within the medical device field. His experience encompasses management of operational, marketing, regulatory, and financial areas on domestic and global stages, with a specialization in successfully meeting both regulatory and business needs. He has earned a degree from the University of Michigan, and an MBA in Healthcare Management. Mr. Robinson has been immersed in the day to day workings of CVR Global over the past eight years, driving progress and growth across all key clinical and operational functions with a focus on both the end user acceptance and market commercialization. Previously, Mr. Robinson was responsible for the management of regulatory activities for a recognized global medical device manufacturer, placing over 25,000 Stock Keeping Units (SKUs) into the healthcare marketplace. Prior to this role, Mr. Robinson was with a top-tier clinical care organization as Director of Marketing.

Tom J. Harris, Chief Financial Officer (CFO)

With a career spanning nearly 50 years, Mr. Harris has held various senior executive roles within both public and non-public companies, including Time Warner, Inc., the Associated Press, and several development stage and start-up entities within the biotech and medical device industries. Mr. Harris played a key role in the successful IPO of American Television and Communications Corporation, predecessor to Time Warner Cable (TWC), as well as leading the effort to decentralize the TWC's operations into several dozen autonomous operating units. While serving as CFO of TWC, Mr. Harris led the efforts to structure, finance, and complete several multi-billions dollar (and smaller) acquisitions, and successfully integrate the acquired businesses into TWC, as well as manage a financing and capital allocation process that resulted in \$5 billion in capital investments to improve and increase TWC's operating footprint.

Tim Knisley, Director of Finance

Mr. Knisley is building CVR Medical's financial systems as they transition from a research and development-based to commercial-ready company with the launch of the CSS device. He has worked in the medical device industry for over twenty years, successfully managing finances and plant controls for several manufacturing companies, including Kendall, Tyco, and the German multinational corporation Beiersdorf AG. With an expert knowledge of medical device company accounting and finance systems, he is focused on preparing CVR Medical for the fundamental shift to revenue and cost structures associated with commercial sales. In addition, he is a certified Lean 6 Sigma Green Belt and Lead Internal Auditor, and his experience with the engineering change notice process and control documentation is expected to provide tangible value to the Company's quality management systems.

Alan Langston, Vice President of Sales and Marketing

Mr. Langston has broad experience in the technology industry in the sales, marketing, and distribution channels, working with leading global manufacturers and original equipment manufacturers (OEMs), such as Kontron America, Panasonic, Arrow Electronics, Avnet, GE, Siemens, and Philips, overdriving sales figures and widening market shares for emerging technologies. During his tenure at Kontron America, the second leading global embedded computer supplier, annual channel sales grew from \$12 million to \$41 million. While with Panasonic's Toughbook division, Langston oversaw similar results, taking a new ISV (independent software vendors) group from \$0 to \$4 million in new opportunities within twelve months. Over the past decade, Mr. Langston has served as a consultant for CVR Medical, becoming well-versed with the CSS and the cardiovascular healthcare landscape. As the anticipated CSS launch rapidly approaches, he has opted to make a full-time commitment to CVR Medical.

Ron Birch, Board Director

Mr. Birch has been President of Big Bar Resources Corporation since November 2008 and served as its CEO until September 2016. He served as President and CEO of Okana Ventures Inc., from May 2005 to June 2008. Mr. Birch has 17 years of experience with the Bank of Nova Scotia in various positions and locations throughout the Province of British Columbia, most recently as Branch Manager in Prince Rupert, B.C. He worked for seven years as a retail stock broker with CM Oliver & Co., Ltd. and Pacific International Securities Inc. in Vancouver. During this time, Mr. Birch also took courses for Options and Commodities and was successful in completing these courses and obtaining certificates and licenses for each. He has been providing consulting services through Janron Consulting Inc. since 1991 and services of a Public Relations Coordinator through Bircress Corporate Relations since 1993. From 1985 to 1991, he was a licensed Stock, Commodities, and Options Broker. Mr. Birch has been a Director of Big Bar Resources Corporation since November 14, 2008. He served as a Director of Okana Ventures Inc. from May 2005 to June 2008 and Jupiter Enterprises Inc. since March 1999.

Benjamin Asuncion, Board Director

Mr. Asuncion has over a decade of experience in the capital markets and resources sector. He was at Haywood Securities Inc., a privately owned Canadian brokerage firm, in equity research from 2007 through to 2016. As a research analyst, he covered companies of varying sizes and stages. Prior to joining Haywood, Mr. Asuncion was involved in the management of an endowment fund at Simon Fraser University (SFU). He holds a Bachelor of Business degree from SFU with concentrations in finance, accounting, and management science. Mr. Asuncion currently holds a senior management position with a publicly listed company.

Dr. Paul Blunden, Board Director, Medical Advisor

Dr. Blunden is a board certified physician in obstetrics and gynecology with over twenty years in practice. Currently, he is the vice president and partner of a large multi-million-dollar multi-provider practice servicing urban, suburban, and rural patients. He has previously served as a department chairman for a major healthcare system and has been a member of the executive leadership committee focused on fiscal management, quality improvement, and recruiting. Dr. Blunden specializes in both micro- and macro-level managerial decision making, with an emphasis on patient care and efficient business/medical coalescing.

Dr. Dallas Hack, Board Director

Dr. Hack has led a decorated medical and military career. Prior to his service with the United States Army Medical Research and Materiel Command (USAMRMC), he developed a background in computer sciences and engineering, and served as Vice President for several biomedical companies. As a brain injury expert, he directed the Combat Casualty Care Research Program (CCCRP) at USAMRMC, where he was accountable for coordinating traumatic brain injury (TBI) research and technology across all Department of Defense groups. From 2008 to 2014, he oversaw projects that received over \$2 billion in grant funding to advance TBI research and technology. His other appointments include Command Surgeon for the Multinational Force in Iraq and, up until his retirement in 2015, Senior Medical Advisor to the Principal Assistant, Research and Technology, USAMRMC.

Dr. Phillip J. Bendick, PhD, Advisory Staff

Dr. Bendick is a prominent medical sonographer and researcher who has been brought on to assist the Company in organizing expanded clinical trials for the CSS device. Dr. Bendick brings a wealth of knowledge and an extensive network to CVR Medical. Since 1971, he has worked, taught, and presented at medical institutions across the world, making seminal contributions to the field of vascular sonography. He has served on the Board of Governors of the American Institute of Ultrasound in Medicine (AIUM), among many other appointments, and has authored over 150 peer-reviewed articles, 15 book chapters and, most recently, held the position of Editor-in-Chief emeritus of the *Journal of Diagnostic Medical Sonography*. Dr. Bendick has spent 40 years using ultrasound to diagnose carotid disease.

Intellectual Property

CVR Medical has established a comprehensive intellectual property (IP) policy that covers several aspects of its CSS device. The Company has one U.S. patent issued (US 9,101,274), 13 patents pending, and more than 20 patents under process. CVR Medical has also established an IP policy to cover all the aspects of the CSS device before product launch. A European Counterpart is pending that parallels the allowed U.S. case. A continuation-in-part, Application No. 14/803,389 is also pending, with a priority date extending back to June 24, 2010. Figure 5 (page 13) summarizes the Company's current IP portfolio.

- In June 2015, CVR Medical filed two applications covering the yoke, utilized for holding the sensors and positioning on a patient, and methods of quantifying and detecting sounds in the carotid artery. Both applications were converted into **Patent Cooperation Treaty (PCT)** applications in June 2016 and await conversion into the U.S. and other jurisdictions. These applications have been assigned to a joint venture (JV), with exclusive licensing remaining with CVR Medical.
- In June 2016, CVR Medical filed five additional provisional patent applications covering several aspects of the CSS device, including additional methods for detecting blockage in a fluid flow vessel, disposable sensing elements (akin to the razor/razor blade model), methods for generating clean data for analysis, methods for detecting sounds and determining stenosis, methods for determining appropriate location for detecting fluid flow in the body, and methods for detecting and ablating stenosis.
- In December 2016, CVR Medical filed an additional provisional application directed towards sensing pods that do not need a yoke in order to position the sensing pods for determining stenosis. In January 2017, CVR Medical 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.

As development continues, CVR Medical expects to further develop and expand its IP portfolio. Additional applications are likely to be filed covering final versions of any product that will go to market. These protections are likely to include patent, design patent, trademark, trade dress, and copyright, where applicable. CVR Medical also expects that the several pending provisional applications will be converted into PCT applications and that the pending PCT applications (now assigned to a JV) will also be converted.

Figure 5
CVR GLOBAL INC. - ACTIVE FILED - PATENT REPORT

Reference #	Title	Serial #	Filed Date	Patent #	Publication #	Publication Date	Issue Date	Status
CVRG0001-100US/363035	SENSOR, SENSOR PAD AND SENSOR ARRAY FOR DETECTING INFRASONIC ACOUSTIC SIGNALS (FORMERLY: 1004215-7007)	13/167,567	6/23/2011	9,101,274	US 20120232427 A1	9/13/2012	8/11/2015	ISSUED
CVRG0009-001P	Method Of Smoothing Data From An Acoustic Signaling Device To Determine Stenosis In The Body							PROPOSED
CVRG0010-001P/363332	METHOD FOR DETERMINING PROPER LOCATION FOR LISTENING TO BODY FLUIDS	62/350,268	6/15/2016					PENDING
CVRG0011-001P/363377	NON-INVASIVE METHOD FOR MEASURING SOUND FREQUENCIES CREATED BY VORTICES IN A CAROTID ARTERY, VISUALIZATION OF STENOSIS, AND ABLATION MEANS	62/350,381	6/15/2016					PENDING
CVRG0012-001P/363333	Stenosis Sensor and Removal Device							PROPOSED
CVRG0013-001P/363334	ATTACHABLE SENSING POD COMPRISING A PIEZOELECTRIC UNIT	62/434,042	12/14/2016					PENDING
CVRG0014-001P/363335	Stenosis Sensor Base And Methods For Determining Replacement Timing Of Components							PROPOSED
CVRG0015-001P	Yoke For Sensing Carotid Stenosis	62/175,913	6/15/2015					EXPIRED
CVRG0015-500PCT/388045	Yoke For Sensing Carotid Stenosis	PCT/US16/37665	6/15/2016		WO2016/205395	12/22/2016		PUBLISHED
CVRG0016-001P/370582	Method For Determining Stenosis In A Carotid Artery Using A Low Frequency Device	62/175,894	6/15/2015					EXPIRED
CVRG0016-500PCT/388051	NON-INVASIVE METHOD FOR MEASURING SOUND FREQUENCIES CREATED BY VORTICES IN A CAROTID ARTERY	PCT/US16/37621	6/15/2016		WO2016/205365	12/22/2016		PUBLISHED
CVRG0017-100	Acoustic Device Cart	29/589,941	1/5/2017					PENDING
CVRG0018-100	Acoustic Listening Yoke	29/589,945	1/5/2017					PENDING
CVRG0001-501P/EP/363036	SENSOR, SENSOR PAD AND SENSOR ARRAY FOR DETECTING INFRASONIC ACOUSTIC SIGNALS (FORMERLY: 1004215-7009)	11754558.2	6/23/2011		EP2585227A1	5/1/2013		PUBLISHED
CVRG0001-001P	SYSTEM APPARATUSES AND PROCESSES FOR INFRASONIC DETECTION OF OCCCLUSION IN ARTERIES (FORMERLY: 1004215-7002)	61/358,202	6/24/2010					EXPIRED
CVRG0001-101CIP/363308	SENSOR, SENSOR PAD AND SENSOR ARRAY FOR DETECTING INFRASONIC ACOUSTIC SIGNALS	14/803,389	7/20/2015		US 20150320323 A1	11/12/2015		PUBLISHED
CVRG0001-500PCT	SENSOR, SENSOR PAD AND SENSOR ARRAY FOR DETECTING INFRASONIC ACOUSTIC SIGNALS (FORMERLY: 1004215-7008)	PCT/US11/41678	6/23/2011		WO/2011/163509	12/29/2011		NAT PHASE
CVRG0001-500CIP/PCT390937	SENSOR, SENSOR PAD AND SENSOR ARRAY FOR DETECTING INFRASONIC ACOUSTIC SIGNALS	PCT/US16/42968	7/19/2016					PENDING
CVRG0002-501P/CA	METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS FOR ANALYZING CARDIAC SOUNDS USING EIGEN	2555838	2/8/2005					ABANDONED
CVRG0002-502P/EP	METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS FOR ANALYZING CARDIAC SOUNDS USING EIGEN	5713055.1	2/8/2005					ABANDONED
CVRG0002-001P	METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS FOR ANALYZING CARDIAC SOUNDS USING EIGEN	60/543,037	2/10/2004					EXPIRED
CVRG0002-500PCT	METHODS, SYSTEMS AND COMPUTER PROGRAM PRODUCTS FOR ANALYZING CARDIAC SOUNDS USING EIGEN	PCT/US05/03873	2/8/2005		WO/2005/077004	8/25/2005		NAT PHASE
CVRG0004-001P/363323	Sensor Device For Sensing Acoustic Signals For Determining Stenosis							PROPOSED
CVRG0005-001P/363328	METHOD FOR DETECTING BLOCKAGE IN A FLUID FLOW VESSEL	62/350,614	6/15/2016					PENDING

Source: CVR Medical Corp.

Potential Milestones

As the Company focuses on transitioning from being a research and development company to a medical device company selling product, the following milestones are expected to take place over the next 12 to 18 months.

- Complete pivotal trials, which is expected near term
- Submit the application to the FDA for market clearance
- Clinical trial investigators publish data analysis
- Final study upon FDA clearance
- Realize sales from devices, which could take place by end of 2Q/1H 2019
- Hire additional personnel in specific areas as the Company prepares for product launch
- Receive mention in approximately 50 upcoming newsletters

Note: All amounts cited in this section are in U.S. dollars unless noted otherwise.

Core Story

CVR Medical Corp. (“CVR Medical” or “the Company”) is a medical technology company developing and advancing novel technology within the healthcare sector to determine carotid arterial health. The Company’s innovative Carotid Stenotic Scan (CSS) device uses low frequency sound wave analysis to detect and measure carotid arterial stenosis (narrowing of the blood vessels in the neck that carries blood from the heart to the brain) or occlusion (the blockage or closing of a blood vessel or hollow organ) for the purpose of identifying patients at risk for ischemic stroke and enabling early intervention.

The screening device, which can be performed in a primary care physician’s office, is non-emissive (does not use harmful radiation to obtain a result), non-invasive, has a small footprint, does not require a certified technician, and can be conducted within a few minutes. As well, it has a per scan price point that is significantly more advantageous as an initial screening tool versus the resource and cost requirements associated with other currently used screening technologies, such as duplex Doppler ultrasound (DUS), magnetic resonance angiography (MRA), computed tomography angiography (CTA), cerebral angiogram, and others, as further detailed on pages 21-23.

There is currently no cost effective, universally accepted method to assess the health of carotid arteries that can be used by a primary healthcare provider. CVR Medical’s CSS device is designed to diagnose cardiovascular health in patients and ensure proper medical treatment at an early stage.

The Company’s CSS is in the clinical phase of development with the final market version being assembled and prepped for pivotal trials, which would be followed by a FDA submission in order to receive market clearance. Upon receiving clearance, the Company expects to initially focus on selling its device into U.S. markets. As well, CVR Medical is negotiating with distribution partners to expand internationally, having recently signed agreements for Chinese and South Korean markets.

The accompanying section provides an overview of carotid artery disease and stroke as an introduction to the market which CVR Medical’s technology is addressing. This is followed by details of the currently used technologies—DUS, MRA, and CTA—and the unique and revolutionary solution that the Company’s CSS is working to commercialize as it seeks to transform the market for vascular diagnostics and improve outcomes.

CAROTID ARTERY DISEASE

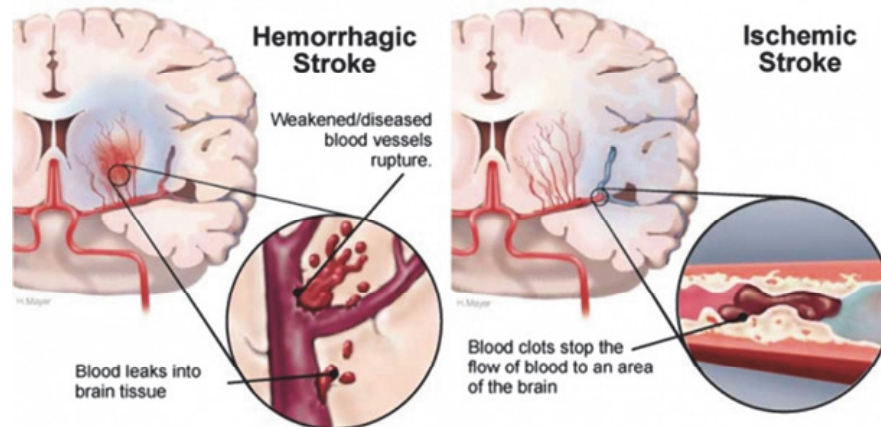
Overview

Carotid artery disease is a condition in which a waxy substance, called plaque, builds up inside the carotid arteries. It is very serious because it can cause a stroke, also called a “brain attack.” A stroke occurs if blood flow to a person’s brain is cut off. There are two common carotid arteries, one on each side of the neck, that each divide into internal and external carotid arteries. The internal carotid arteries supply oxygen-rich blood to a person’s brain; the external carotid arteries supply oxygen-rich blood to the face, scalp, and neck.

A stroke occurs when the flow of oxygen-rich blood to a portion of the brain is blocked. Deprived of oxygen, brain cells begin to die after only a few minutes. As well, sudden bleeding in the brain can cause a stroke if it damages brain cells. If brain cells die or are damaged due to a stroke, symptoms can occur in the parts of the body that these brain cells control. Such symptoms may include sudden weakness; paralysis or numbness of the face, arms, or legs; trouble speaking or understanding speech; and difficulty seeing. As a very serious medical condition, stroke requires immediate emergency care as it can cause lasting brain damage, long-term disability, or even death.

The two main types of stroke are ischemic and hemorrhagic, where ischemic is the more common type of stroke (87% of stroke incidents are ischemic versus 13% which are hemorrhagic). An ischemic stroke occurs if an artery that supplies oxygen-rich blood to the brain becomes blocked. Blood clots typically can cause the blockages that lead to ischemic strokes. In comparison, a **hemorrhagic stroke** occurs if an artery in the brain leaks blood or ruptures (breaks open) and the pressure from the leaked blood damages brain cells. High blood pressure and **aneurysms** are conditions that can cause hemorrhagic strokes. Figure 6 illustrates the difference between the two types of strokes.

Figure 6
HEMORRHAGIC VERSUS ISCHEMIC STROKE



Source: Heart and Stroke Foundation of Canada.

Importantly, when a person has a **thrombosis** on the artery wall, these plaques are very hard and very sharp. When a patient gets a **systole** event, it will produce sharp edges and cut into the artery wall, bleeding **dirty blood** into that wall, which will clot and then continue to clot. This can be compared to an icicle growing, where the water comes down and it gets longer and longer. When it gets long and heavy enough, it breaks off. The is the same situation with a blood clot. In 33% of cases of patients who experience an ischemic stroke, it is caused by a thrombosis, which goes to the brain.

Another condition that is similar to a stroke is a transient ischemic attack (also called a TIA or mini-stroke, depicted in Figure 7). A TIA occurs if blood flow to a portion of the brain is blocked only for a short time and damage the brain cells is not permanent. Similar to ischemic strokes, TIAs are often caused by blood clots. While not full-blown strokes, TIAs greatly increase the risk of having a stroke. Symptoms of TIAs include weakness on one side of the body, vision problems, and slurred speech, though these symptoms are transient and often resolve within 24 hours. As such, it's crucial for a physician to determine the cause of the TIA in order to take necessary measures to prevent another TIA or stroke. In either situation, both strokes and TIAs require emergency care.

According to the CDC, in one survey, 93% of respondents recognized sudden numbness on one side as a symptom of stroke, though only 38% were aware of all major symptoms and knew to call 911 when someone was having a stroke. (Source: Fang J, Keenan NL, Ayala C, Dai S, Merritt R, Denny CH. Awareness of stroke warning symptoms—13 states and the District of Columbia, 2005. *MMWR* 2008;57:481–5). The reason that recognizing the signs and symptoms is so critical is that patients who arrive at the emergency room within three hours of their first symptoms often have fewer disabilities three months after a stroke than those whose care was delayed, as they are able to receive immediate treatment with medications, such as tPA (blood thinners), which can minimize brain damage.

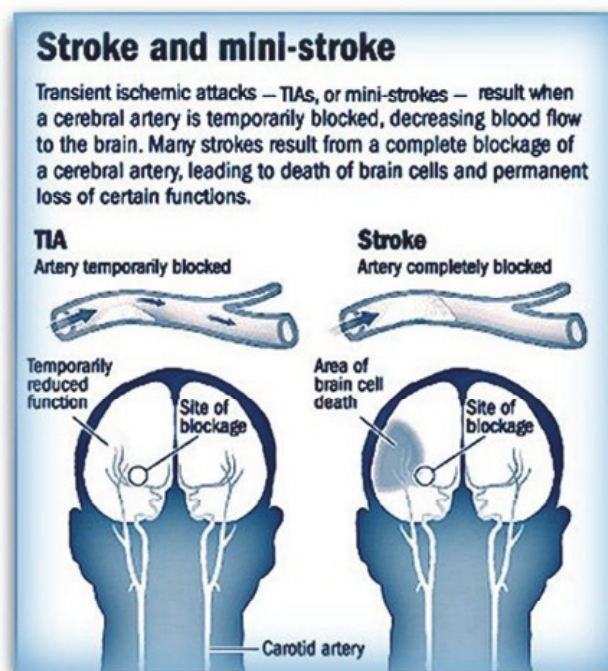
Statistics

In the U.S., more than 795,000 people experience a stroke every year, where approximately 610,000 of these are first or new strokes. About 185,000 of these—roughly one in four—are in people who have had a previous stroke. Stroke kills approximately 140,000 Americans every year, which equates to one out of every 20 deaths. Every 40 seconds someone in the U.S. has a stroke and every four minutes someone dies from a stroke (Figure 8, page 18). The leading cause of death is cardiovascular disease, in which roughly 735,000 American's suffer a heart attack every year, resulting in 610,000 deaths (one in every four deaths).

While the incidence of strokes and heart attacks is roughly the same, stroke is the leading cause of disability; 50% of victims end up with lifelong disability and in 12% of people, it proves fatal, whereas 83% of heart attack victims die. Stroke is the fifth leading cause of death for Americans, however, risk varies by race and ethnicity, with the risk of having a first stroke nearly twice as high for blacks as it is for whites, and where blacks have the highest rate of death due to stroke. While stroke death rates have declined for decades among all race/ethnicities, Hispanics have seen an increase in death rates since 2013. Worldwide, according to the World Health Organization (WHO) 15 million people suffer a stroke each year, and of these, 5 million people die and another 5 million are permanently disabled.

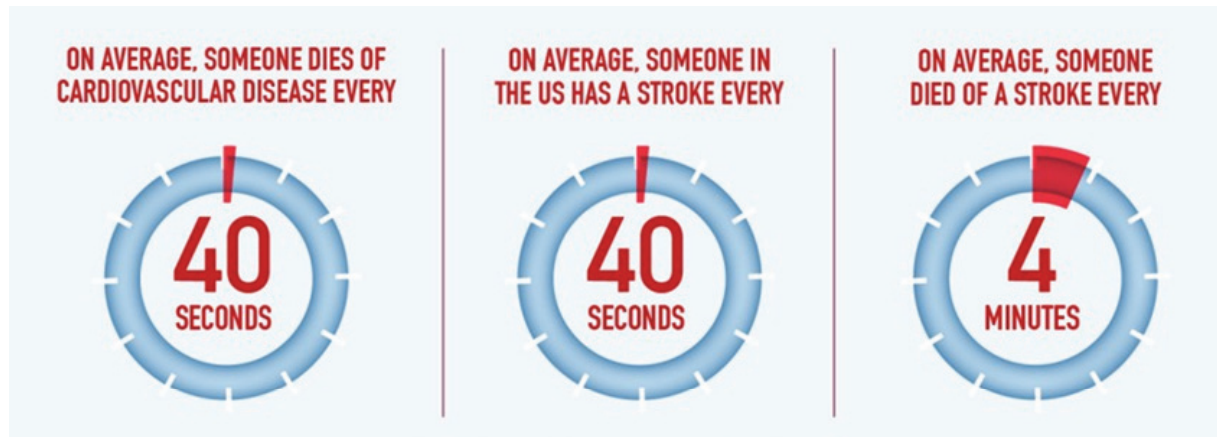
Stroke costs the U.S. an estimated \$34 billion each year and an estimated \$71.6 billion worldwide. This total includes the cost of healthcare services, medicines to treat stroke, and missed days of work. As a leading cause of serious long-term disability, stroke reduces mobility in more than half of survivors age 65 and over. Risk of stroke increases with age, however, it can—and often does—occur at any age. In 2009, 34% of people hospitalized for stroke were under the age of 65.

Figure 7
STROKE VERSUS MINI STROKE (TIA)



Source: braininjury-explanation.com Foundation.

Figure 8
KEY STROKE STATISTICS



Source: American Heart Association Statistical Update, 2017.

The financial cost of strokes is immense and could soar from current levels of approximately \$71.6 billion worldwide to more than \$2.2 trillion by 2050 if no action is taken to improve preventive care or treatment, according to a study published in *Neurology* (the scientific journal of the American Academy of Neurology). About half of the stroke-related costs by 2050, including treatment, rehabilitation, and lost wages, will come from stroke patients under the age of 65. It is possible that the \$2.2 trillion economic burden could prove to be a conservative estimate since it is based on current rates of the conditions that put people at risk for stroke, such as diabetes, heart disease, and obesity, which are currently on the rise. Figure 9 provides a key overview of stroke/carotid artery disease, summarizing these key statistics.

Figure 9
STROKE/CAROTID ARTERY DISEASE OVERVIEW

Currently there is no cost effective way to screen for ischemia of the carotid artery, which is the leading indicator of stroke.

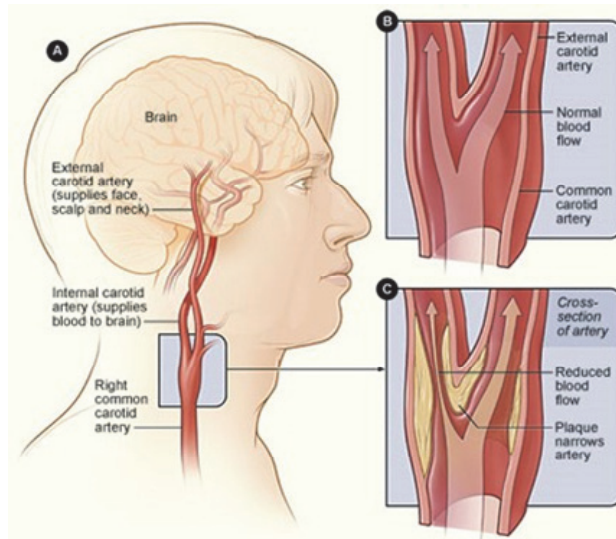
- Leading cause of disability (Globally)
- 5th leading cause of death (U.S. 2015)
- 795,000 stroke incidents yearly (USA - 2013)
 - 87% Ischemic
 - 13% Hemorrhagic

Stroke Results (Globally)

- 50% Permanent impairment
- 38% Recover
- 12% Fatal

Cost

- 2017: \$34 Billion (U.S.)
- 2010: \$71.6 Billion (Globally)
- 2030: Cost Estimated to Triple



Source: CVR Medical Corp. and Centers for Disease and Prevention.

Causes

Ischemic Stroke and Transient Ischemic Attack (TIA)

A variety of medical conditions can increase the risk of ischemic stroke or TIA. Atherosclerosis, for example, is a disease in which a fatty substance, called plaque, builds up on the inner walls of the arteries, hardens, and then narrows the arteries, limiting the flow of blood to tissues and organs (such as the heart and brain). Blood platelets stick to the site of the plaque injury and clump together to form blood clots, which can partially or fully block an artery. Plaque can build up in any artery in the body, including arteries in the heart, brain, and neck. In particular, the two main arteries on each side of the neck are called the carotid arteries and it is these arteries that supply oxygen-rich blood to the brain, face, scalp, and neck. When plaque builds up in the carotid arteries (carotid artery disease), this can lead to ischemic strokes and TIAs. Having plaque buildup in the carotid arteries may also mean that a person has plaque buildup in other arteries. As a result, people who have carotid artery disease also are at greater risk for coronary heart disease.

An **embolic stroke** can occur if a blood clot or piece of plaque breaks away from the wall of an artery. When this happens, the clot then travels through the bloodstream and can get stuck in one of the brain's arteries, stopping the blood flowing through the artery and damaging brain cells. Heart conditions and blood disorders can further cause blood clots that can lead to a stroke or TIA. One such example, **atrial fibrillation (AF)**, is a common cause of embolic stroke. In AF, the upper chambers of the heart contract in a very fast and irregular way, resulting in some blood pooling in the heart, which heightens the risk of blood clots developing within the hearts chambers. An ischemic stroke or TIA can result from lesions caused by atherosclerosis, where these lesions may form in the small arteries of the brain, cutting off blood flow to the brain.

Hemorrhagic Stroke

Sudden bleeding in the brain can cause a hemorrhagic stroke, in which the bleeding causes swelling of the brain and increased pressure in the skull. Such swelling and pressure can damage brain cells and tissues. Conditions that can cause a hemorrhagic stroke include high blood pressure, aneurysms, and **arteriovenous malformations (AVMs)**. As the heart pumps blood, blood pressure is the force that pushes blood against the walls of the arteries. When blood pressure rises and stays elevated for a period of time, it can injure the body in a variety of ways, including aneurysms and AVMs. High blood pressure increases the risk of hemorrhagic stroke in people who have aneurysms or AVMs.

Risk Factors

The leading risk factors for stroke and carotid artery disease also are the main risk factors for coronary heart disease and peripheral artery disease, as described below.

- **Diabetes.** The body's blood sugar level is too high because the body is not able to make enough insulin or is not able to use its insulin properly. People who have diabetes are four times more likely to have carotid artery disease than people who do not have diabetes.
- **Family history.** People who have a family history of atherosclerosis are more likely to develop carotid artery disease.
- **High blood pressure (Hypertension).** Blood pressure is considered high if it stays at or above 140/90 mmHg over time. In patients with diabetes or chronic kidney disease, high blood pressure is defined as 130/80 mmHg or higher.
- **Lack of physical activity.** Too much of a sedentary lifestyle and a dearth of aerobic activity can make other risk factors for carotid artery disease worse, such as unhealthy blood **cholesterol** levels, high blood pressure, diabetes, and obesity.

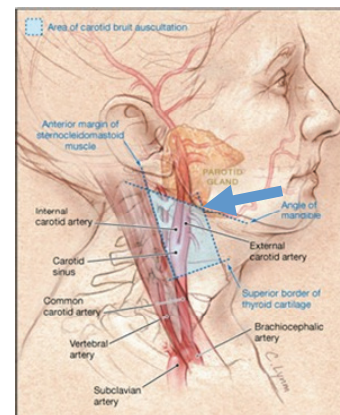
- **Metabolic syndrome.** The name for a group of factors that raise the risk for stroke and other health problems, such as diabetes and heart disease. The five metabolic risk factors include a large waistline (abdominal obesity), a high triglyceride level (a type of fat found in the blood), a low HDL cholesterol level, high blood pressure, and high blood sugar. Metabolic syndrome is diagnosed if an individual has at least three of these metabolic risk factors.
- **Older age.** Risk for atherosclerosis increases as people age. The process of atherosclerosis begins in youth and typically advances over several decades prior to the disease manifesting.
- **Overweight or obesity.** The terms “overweight” and “obesity” refers to body weight that is greater than what is considered healthy for a certain height.
- **Smoking.** Smoking can damage and tighten blood vessels, lead to unhealthy cholesterol levels, and raise blood pressure. It can also restrict the amount of oxygen that reaches the body’s tissues.
- **Unhealthy blood cholesterol levels.** These levels include high **LDL (bad) cholesterol** and low HDL (good) cholesterol.
- **Unhealthy diet.** An unhealthy diet can increase carotid artery disease risk. Foods that are high in saturated and trans fats, cholesterol, sodium, and sugar can worsen other risk factors for carotid artery disease.

Signs and Symptoms

Signs or symptoms of carotid artery disease may not present until a carotid artery is severely narrowed or blocked, which is the reason that early diagnosis is such a critical part of enabling early intervention for treatment. Symptoms may include a bruit, a TIA, or a stroke, as described below.

- **Bruit.** In the middle of the neck is the **bifurcation** from the common carotid to the internal and external carotid artery. To be able to hear the external carotid artery, a physician places the stethoscope somewhere near the middle front part of a patient’s throat (Figure 10). What is being listened for is something called a bruit—the swishing sound that can happen from a blockage. During a physical exam, a doctor may listen to the patient’s carotid arteries to detect a bruit as it may suggest changed or reduced blood flow due to plaque buildup. Although not all people who have carotid artery disease have bruits, if one is detected, a doctor may recommend further testing.
- **TIA (Mini-Stroke).** A TIA or “mini-stroke” is the first sign of carotid artery disease for some individuals. A mini-stroke may manifest with some or all the symptoms of a stroke, however these symptoms typically go away on their own within 24 hours. Stroke and mini-stroke symptoms may include a sudden, severe headache with no known cause; dizziness or loss of balance; inability to move one or more of limbs; sudden trouble seeing in one or both eyes; sudden weakness or numbness in the face or limbs (often on just one side of the body); and trouble speaking or understanding speech. A mini-stroke is a warning sign that an individual may be at high risk of having a stroke; thus getting medical care to find a possible cause helps to manage risk factors and ultimately could prevent a future stroke. Importantly, while a mini-stroke may warn of a stroke, it does not predict when it will happen.
- **Stroke.** While the results are different, symptoms of a stroke are the same as those of a mini-stroke. A stroke can cause lasting brain damage; long-term disability, including vision or speech problems or paralysis (an inability to move); or death. Most people who have strokes have not previously had warning mini-strokes. The best chance for full recovery generally comes when treatment to open a blocked artery is given within three to four hours of symptom onset (where the sooner treatment occurs, the better the chances of recovery).

Figure 10
AREA OF CAROTID BRUIT AUSCULTATION



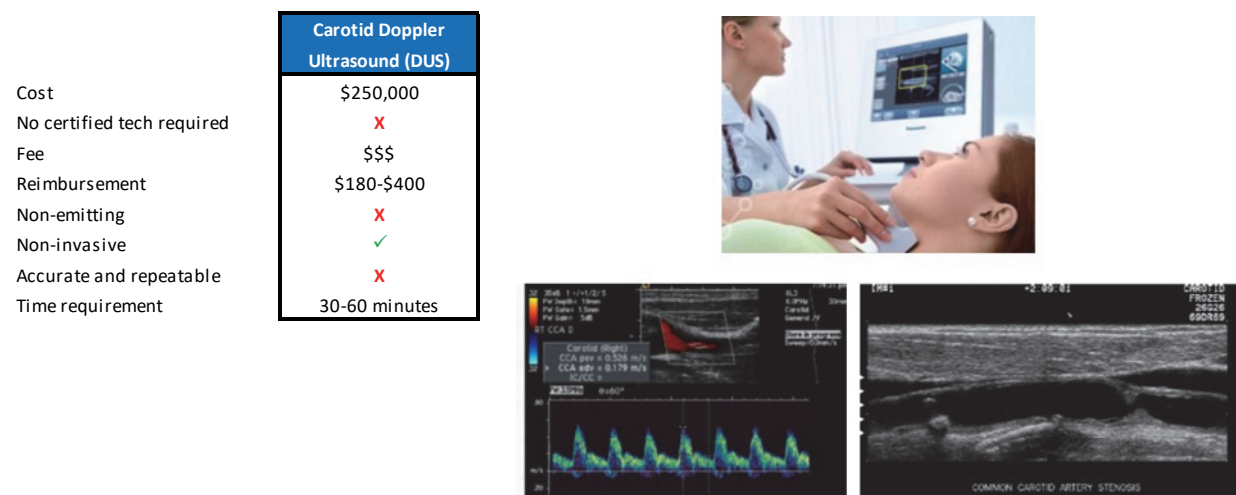
Source: Simel DL, Rennie D: *The Rational Clinical Examination: Evidence-Based Clinical Diagnosis*: <http://jamaevidence.com>.

Current Diagnostics

In order to make a stroke diagnosis, a physician must learn as much as possible about a patient's symptoms, current and previous medical problems, current medications, and family history. The physician also performs a physical exam to listen to the carotid artery with a stethoscope in order to attempt to detect a bruit. Based on information gathered from the above, the patient may be sent on for further diagnostic tests to determine whether there is narrowing of the carotid arteries. Currently, carotid stenosis can be diagnosed by either a DUS, CTA, or MRA, as described below and on the accompanying pages. Imaging can also reveal evidence of multiple small strokes.

- Duplex Doppler Ultrasound (DUS).** DUS is the most common test to diagnose carotid artery disease. This painless, harmless test uses sound waves to create pictures of the insides of the carotid arteries to show whether plaque has narrowed the carotid arteries, and if it has, how narrow they are. A standard carotid ultrasound shows the structure of the carotid arteries; a duplex Doppler carotid ultrasound shows how blood moves through the carotid arteries (Figure 11). The test takes approximately 30 to 60 minutes and is done in an ultrasound lab.

Figure 11
CAROTID DOPPLER ULTRASOUND


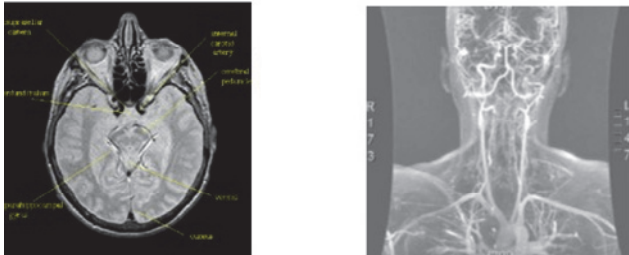


Source: CVR Medical Corp.

- Magnetic Resonance Angiography (MRA).** MRA employs a large magnet and radio waves to take pictures of the carotid arteries, where these pictures can be viewed on a computer screen. Contrast dye may be given to the patient to highlight the carotid arteries on the pictures. MRA is most often used to examine vessels in the brain, neck, kidneys, and legs (Figure 12). The test takes under an hour and is done in either a lab or hospital setting.

Figure 12
MAGNETIC RESONANCE ANGIOGRAPHY

	Magnetic Resonance Angiography (MRA)
Cost	\$1 mm - \$2.5 mm
No certified tech required	X
Fee	\$\$\$\$
Reimbursement	\$3,000
Non-emitting	X
Non-invasive	✓
Accurate and repeatable	X
Time requirement	>60 minutes


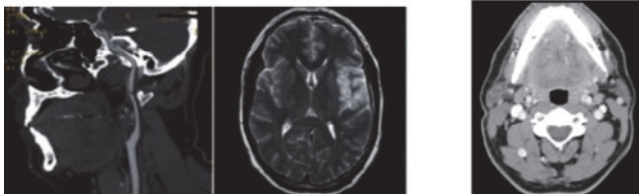



Source: CVR Medical Corp.

- Computed Tomography Angiography (CTA).** CTA angiography takes X-ray pictures of the body from many angles, and a computer then combines the pictures into two- and three-dimensional images (Figure 13). As with other tests, dye may be injected into the patient to highlight the carotid arteries on the pictures.

Figure 13
COMPUTED TOMOGRAPHY ANGIOGRAPHY

	Computed Tomography Angiography (CTA)
Cost	\$1 mm - \$2.5 mm
No certified tech required	X
Fee	\$\$\$\$
Reimbursement	\$500 - \$1,500
Non-emitting	X
Non-invasive	✓
Accurate and repeatable	X
Time requirement	30-60 minutes

Source: CVR Medical Corp.

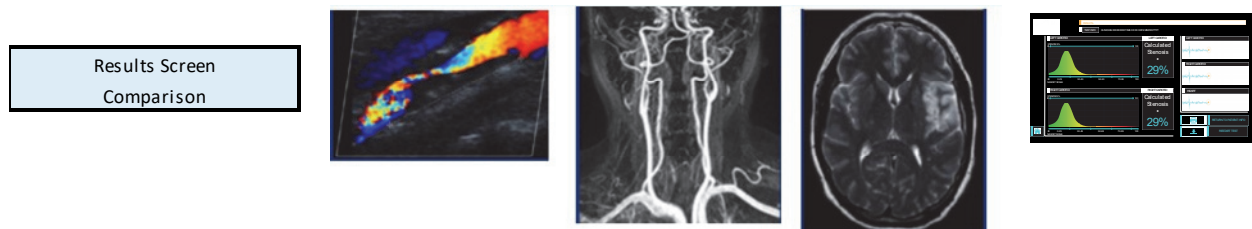
- Cerebral angiogram.** This diagnostic test uses an X-ray to find blockages or other abnormalities in the blood vessels of the head and neck. A patient is injected with contrast medium to help create a clean picture of the blood vessels on the X-ray.

A summary comparison between the most commonly used diagnostics is provided in Figure 14 (page 23) as it compares to CVR Medical’s CSS technology, which is further detailed in the accompanying section (pages 23-24).

Figure 14

CURRENT DIAGNOSTICS LANDSCAPE AND POTENTIAL NEW SOLUTION

	Carotid Doppler Ultrasound (DUS)	Magnetic Resonance Angiography (MRA)	Computed Tomography Angiography (CTA)	Carotid Stenotic Scan (CSS)
Cost	\$250,000	\$1 mm - \$2.5 mm	\$1 mm - \$2.5 mm	\$49,000
No certified tech required	X	X	X	✓
Fee	\$\$\$	\$\$\$\$	\$\$\$\$	\$
Reimbursement	\$180-\$400	\$3,000	\$500 - \$1,500	\$105*
Non-emitting	X	X	X	✓
Non-invasive	✓	✓	✓	✓
Accurate and repeatable	X	X	X	✓
Time requirement	30-60 minutes	>60 minutes	30-60 minutes	2 minutes



Source: CVR Medical Corp.

THE POTENTIAL DILEMMA WITH CURRENT DIAGNOSTICS

A primary care physician currently does not have the tools in the office to be able to assess a patient’s carotid arterial health as the equipment typically used to do so—DUS, MRA, and CTA’s—requires a large space and licensed personnel to operate. Therefore, a patient’s arterial health is only checked when a patient presents clear signs and symptoms of a stroke—such as a physician’s ability to hear a bruit in the external carotid artery, along with being symptomatic. Research over the last several decades has shown that a bruit has no bearing on a person’s propensity for having a stroke, yet today, it remains the modality for physicians before sending a patient off for a detailed diagnostic. Thus, in order to have the laboratory receive reimbursement, there must be a prescription written for a bruit, as well as all of the other indicators. However, when a patient has only one symptom, while it could be a stroke, it could also be anything from a headache or otherwise, and in this case, the patient could be called asymptomatic. At this point, an important decision must be made as to how to treat this patient.

If the primary care physician makes the decision for further testing, the patient is sent to a lab for diagnostic testing. Following testing, the lab may recommend that the patient be seen by a cardiovascular specialist, likely one that is working with that lab. At that point, the primary care physician may lose that patient to the cardiovascular specialist (with many patients then going on to use the cardiologist as their primary care doctor). This scenario is depicted in Figure 15.

Figure 15

CURRENT MODALITIES



Source: CVR Medical Corp. and Crystal Research Associates, LLC.

The next problem is that because the primary care physician currently does not have the technology available in the office to diagnose a stroke, when the patient is sent for testing, data may come back to the primary care doctor indicating either under 50% or over 50% stenosis. The problem with this is when a patient presents with several indicators and is above 50% stenosis, the patient must be sent on to a cardiologist despite the possibility that there may not be a problem (creating a false positive point). When a patient is just below 50% stenosis, and where the accuracy of that duplex Doppler ultrasound is not nearly as good as the patient thinks it is, this may either be a false negative or false positive situation.

An added dilemma is that in a large percentage of states, primary care doctors may not get reimbursed for a diagnostic procedure. In order to receive reimbursement in a primary care office, it must be an Intersocietal Accreditation Commission (IAC) imaging facility or hospital specific to vascular testing. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide. It takes a great deal of care to have this and requires a very highly skilled certified technician, which is the reason most primary care physicians are not part of the IAC program.

CVR Medical's proprietary low frequency sound wave analysis technology has been developed for use in a primary care physician office to initially identify the need for intervention before the occurrence of stroke and at a cost that is much lower than currently employed arterial screening tools. There is currently no cost effective and universally accepted way to detect and measure blockage within carotid arteries by the primary healthcare provider.

Outcomes of Current Diagnostic Process

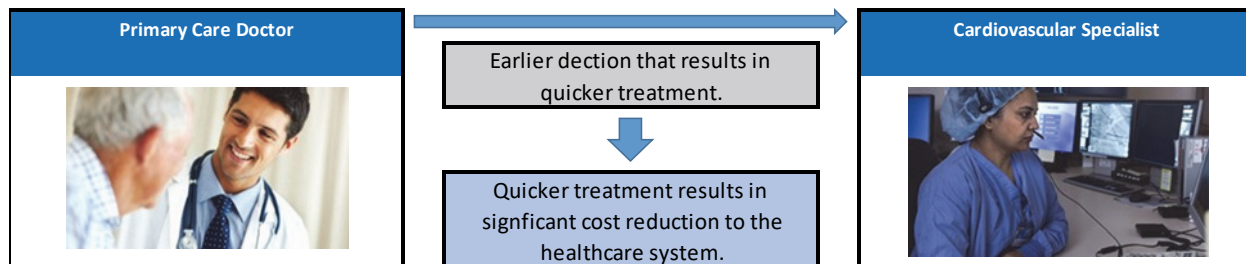
Normal protocols used to determine a person's risk of stroke entail a patient going to his or her primary care physician and the physician asking a series of questions of first indicators—usually during an annual physical. The physician also listens for a bruit. When there is any interference, there may be a swishing sound. The problem with this process is that the false negative level—where a patient goes through this methodology and ends up not having an intervention—is 20%. The false positive is also 20% of patients going through the same process who end up on an operating table. Accordingly, this process is not only very costly to the medical system, but also to the patients themselves, where approximately 12% of all people who have a stroke end up dying; 50% become permanently incapacitated (needing 24-hour care), and the remainder (38%) end up recovering either fully or to some degree where they are still able to take care of themselves.

THE CSS SOLUTION

CVR Medical’s Carotid Stenotic Scan (CSS) technology has been developed for use in a primary care physician’s office to immediately detect and identify a problem at the point of care. Having demonstrated to be accurate and repeatable within clinical trials, the CSS can provide the precise information to determine whether a patient goes on to see a cardiovascular specialist for further testing, or in roughly half the cases, is prescribed a drug (such as a statin) with results showing that the patient is not a candidate at that point for an ischemic stroke (Figure 16).

Figure 16

THE SOLUTION: CAROTID STENOTIC SCAN (CSS) IMPLEMENTATION



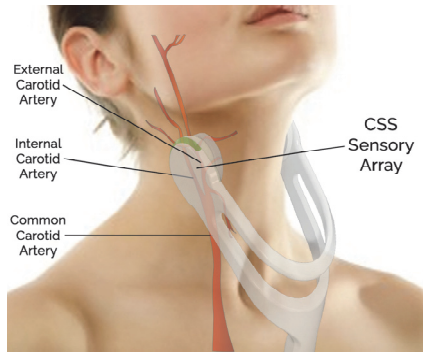
Source: CVR Medical Corp. and Crystal Research Associates, LLC.

The CSS technology, which is non-invasive, non-emitting, and has a small footprint in the physician’s office, is capable of quickly determining the percentage of stenosis or blockage in a carotid artery—which is the leading indicator for risk of stroke. Importantly, the Company is currently not able to state that the device can determine an individuals’ actual risk for stroke since, under regulatory guidelines, this cannot be stated unless it can be proven. The CSS device has demonstrated to not only be a potential lifesaver for the patient but also becomes a profit center for the primary care physician and a money saver for the payor (where the payors will significantly reduce their costs for running unnecessary laboratory diagnostic testing). These reduced costs of stroke include reduced costs of false positives and reduced costs of all the necessary imaging (specifically since CVR Medical is able to test every adult over the age of 20 and create a baseline).

The Science Behind the CSS Technology

Designed to assess blockages or stenosis in the carotid arteries, the Company’s technology is critical as symptoms of a stroke do not often manifest until it is too late. CVR Medical’s innovation makes it quick and easy to identify patients who are at risk prior to a stroke but before they show any symptoms. Illustrated in Figure 17 (page 26), the CSS is able to diagnose the presence of cardiovascular disease by analyzing the sound waves produced by the blood flow through the carotid arteries. Developed in cooperation with the Army Research Lab under a Cooperative Research and Development Agreement, proprietary sensors provide low frequency acoustic coupling from the carotid arteries to the CSS. When blood normally flows within an artery or a vein, it creates sound waves at a particular frequency. Narrowing of the blood vessel due to plaque buildup or the presence of a blockage creates a change in the blood pressure and in the frequency of the sound waves produced by the blood flow. These changes can be analyzed by the device to assess the carotid arterial health of the patient. Comparing input from sensors, the CSS improves accuracy and eliminates variances in anatomical structure, including blood speed, size of artery, temperature of blood, hematocrit of blood, and elasticity of arterial wall.

Figure 17
CAROTID STENOTIC SCAN (CSS)

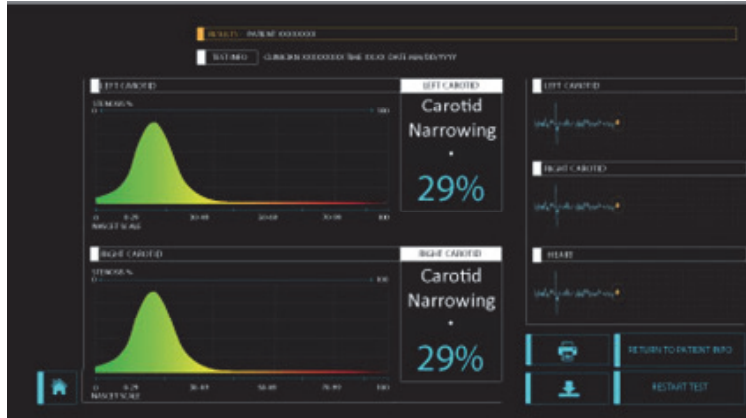


- Sensors developed in a CRADA with the DOD Army Research Lab
- Sensors provide low frequency acoustic coupling delivering data from the carotid arteries to the CSS
- Listens to blood flow in the carotid arteries
- Analyzes data into a percentage of stenosis

Source: CVR Medical Corp.

The analysis is made possible with the aid of special sensors employed within the CSS device. When the sensors are placed over the carotid arteries of the patient during a two-minute procedure, they enhance the acoustic characteristics of the blood flow. These sound patterns are captured and analyzed mathematically by making use of the Company’s patented algorithms. The analysis produces accurate results on the percentage of stenosis or blockage along with a detailed interpretation regarding the presence of blockage or stenosis on the inner surface of the carotid artery (shown in Figure 18).

Figure 18
THE CAROTID STENOTIC SCAN (CSS) RESULTS REPORT



Source: CVR Medical Corp.

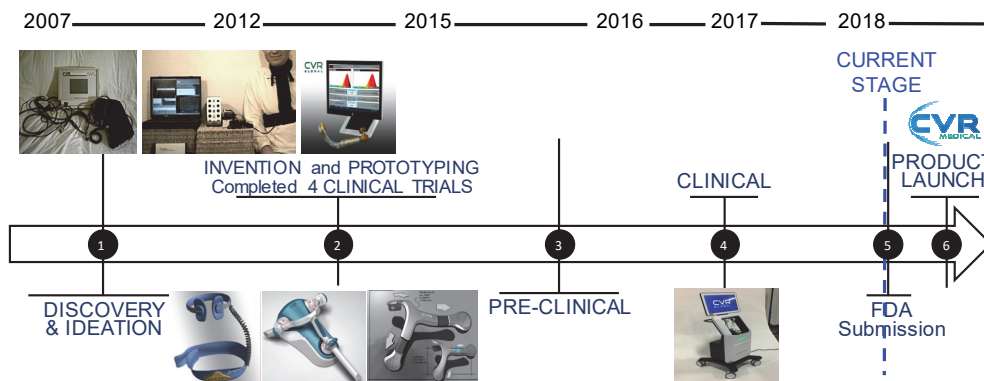
FDA Status

In early May 2018, CVR Medical announced the receipt of official meeting minutes for their Pre-Submission meeting on March 23, 2018 with the U.S. FDA regarding the CSS device and its upcoming FDA submission for market release. Attendees of the meeting included CVR management, regulatory consultant’s Duval & Associates, and key reviewers from the FDA. The purpose of the meeting was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing. 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.

Expected Launch 1H 2019

The Company’s CSS device is in the final clinical phase of development, with CVR Medical preparing for submission to the FDA and a potential for targeted launch of 1H 2019, and selling potentially soon after. The regulatory pathway for CVR Medical’s product launch as it compares to the regulatory pathway (time and cost to market) for a pharmaceutical drug is summarized in Figures 19 and 20 as a point of comparison.

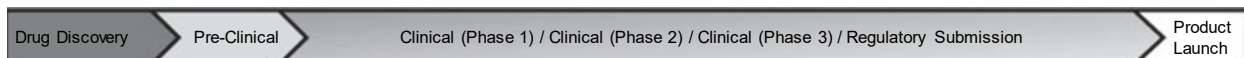
Figure 19
CSS TIMELINE



CSS Targeted Market Launch: 11 Years
 CSS Cost To Market Launch: \$45,000,000 (USD)

Source: CVR Medical Corp.

Figure 20
DRUG TIMELINE (NOT CSS)



Time To Market: Up To 15 Years

Source: CVR Medical Corp.

Thomas Jefferson University Hospital Clinical Trial Results

CVR Medical announced in June 2017 that Thomas Jefferson University Hospital (Jefferson Clinical Research Institute) issued an initial trial report summarizing the clinical trial progress of the CSS under the supervision of principal investigator, Dr. David Whellan, MD, MHS, FACC, FAHA. The ENTICES (Evaluation of a Novel Technique to Investigate CAS piezo-Electric Sensors) Study, assessing CSS against current ultrasound technology, is enrolling at a robust pace with data on over 125 patients. A major factor in the successful enrollment, which began in January 2017, has been the ease at which CSS data can be acquired, allowing participants to have test studies performed quickly.

As the first study evaluating the CSS technology, the overall objectives of this study are to determine that the CSS can accurately detect significant carotid artery stenosis. A secondary objective is to relate changes in CSS signal to different degrees of stenosis. “Proof of concept” is obtained if the device correlates strongly with the established classification of atherosclerotic carotid disease derived from various imaging modalities, including DUS, MRA, CTA, conventional angiography, or carotid ultrasound.

Carotid duplex ultrasound uses B-mode ultrasound imaging and duplex Doppler ultrasound to detect focal increases in blood flow, velocity indicative of high grade carotid stenosis. It is noninvasive, safe, and relatively inexpensive. Compared to intra-arterial cerebral angiography, ultrasound has a sensitivity of 81% to 98% and a specificity of 82% to 89%. Results presented in this report represented the first 109 carotid ultrasound subjects' testing for the primary objective, which was to assess the association between carotid artery stenosis as measured by CSS and carotid ultrasound. The CSS device measured the degree of stenosis in the left and right carotid arteries of the subjects, with results then compared to clinical ultrasound examinations.

Figure 21 reports the demographic characteristics for the first set of subjects, including the hospital-based location of the radiology ultrasound setting; Figure 22 reports the enrollment metrics to date; Figure 23 (page 29) reports the measurement values for the left and right carotid arteries as reported by the CSS device and by radiology-reported clinical ultrasound exam; and Figure 24 (page 29) shows results from a July 2017 clinical report summary from Thomas Jefferson University Hospital as interpreted by CVR Global.

Figure 21
CHARACTERISTICS OF SUBJECTS CONSENTED FOR CSS/CVR GLOBAL STUDY (n=109)

Variable	n (%)
Female	51 (47)
BMI (m±SD)	28.1 ± 5.96
Age (m±SD)	67.2 ± 13.6
Race	
White	78 (71.56)
Black	28 (25.70)
Other	3 (2.75)
Medical History	
Ischemic Heart Disease	21 (19.27)
Myocardial Infarction	17 (15.60)
Heart Failure	6 (5.50)
Peripheral Arterial Disease	13 (11.93)
TIA	12 (11.01)
Stroke	15 (13.76)
Diabetes	25 (22.94)
Hypertension	70 (64.22)
Hyperlipidemia	60 (55.05)
COPD	10 (9.17)
Enrollment Location	
General Radiology	64 (58.72)
Vascular Radiology	34 (28.44)
Impatient	14 (12.84)

Source: Jefferson Clinical Research Institute.

Figure 22
ENROLLMENT METRICS

Milestone	Date
1st patient enrolled	2/3/2017
Exclusion criteria revised to include pre-post-op subjects	5/8/2017
Most recent patient included in analysis enrolled	6/8/2017
Overall enrollment rate	6.06 pts per week
Enrollment rate before exclusion criteria change	4.84 pts per week
Enrollment rate after exclusion criteria change	9.94 pts per week

Source: Jefferson Clinical Research Institute.

Figure 23
CSS AND CLINICAL EXAM REPORTED VALUES

Left Carotid Results	
CSS Reported Results Left Carotid (m ± SD)	30.30 ± 21.46
CSS Results Left Carotid (Categorical)	
<50% Stenosis	87 (79.82)
50-69% Stenosis	17 (15.60)
70-99% Stenosis	5 (4.59)
Clinical Exam Results Left Carotid (Categorical)	
<50% Stenosis	93 (85.32)
50-69% Stenosis	8 (7.34)
70-99% Stenosis	4 (3.67)
>99% Stenosis	2 (1.83)
Not Reported	2 (1.83)
Right Carotid Results	
CSS Reported Results Right Carotid (m ± SD)	24.53 ± 17.95
CSS Results Right Carotid (Categorical)	
<50% Stenosis	102 (93.58)
50-69% Stenosis	5 (4.59)
70-99% Stenosis	2 (1.83)
Clinical Exam Results Right Carotid (Categorical)	
<50% Stenosis	93 (85.32)
50-69% Stenosis	12 (11.01)
70-99% Stenosis	2 (1.83)
>99% Stenosis	1 (0.92)
Not Reported	1 (0.92)

Source: Jefferson Clinical Research Institute.

Figure 24
THOMAS JEFFERSON UNIVERSITY HOSPITAL
JULY 2017 CLINICAL REPORT SUMMARY AS INTERPRETED BY CVR GLOBAL INC.

Clinical Trial Results	CSS (Left)	DUS (Left)	CSS (Right)	DUS (Right)
< 50% Stenosis	87	93	102	93
≥ 50% Stenosis	22	14	7	15

Totals	Scans
DUS	215
CSS	215

CSS Correlation:

Agreement	184
Disagreement	31

CSS: Carotid Stenotic Scan
DUS: Duplex Doppler Ultrasound

Source: Jefferson Clinical Research Institute.

Advisory staff member Dr. Phillip J. Bendick, PhD (biography on page 11), released a summarized report in September 2017 on data from the tertiary clinical trials for the CSS device at Thomas Jefferson University, viewing the initial evaluations as successful and confirming the device’s value and efficiency.

“From a clinical standpoint [...] the most important point is likely that the CSS, in a statistical sense, is very specific,” state Dr. Bendick. Nearly all of the tested patients that had carotid artery stenosis were identified without an “overread,” an important measure which allows doctors to recommend steps for further care with confidence...“From a development standpoint [...] the greatest value of this latest data is the guidance it has provided in signal analysis.”

CVR Medical is in the process collecting pivotal trial data from Thomas Jefferson University Hospital, which is intended to be used in the upcoming FDA submission to substantiate the safety and efficacy of the Carotid Stenotic Scan (CSS).

Henry Ford Hospital Clinical Trials

CVR Medical announced on January 23, 2018 the commencement of clinical data acquisition by the CSS device at Michigan’s Henry Ford Hospital. There is currently one wireless CSS device fully deployed within the Henry Ford system and two additional devices slated for implementation in coming weeks. This clinical trial plays a crucial role in accelerating substantiation for the CSS device and shortening the timeline for the Company’s FDA submission. The team at Henry Ford possesses the expertise and experience necessary to successfully validate the worth of the CSS device, having been recognized for its excellence in the area of cardiology and cardiovascular surgery. The trial will be overseen by primary investigator, Dr. Judith Lin, Senior Staff Surgeon and Medical Director of Henry Ford’s Clinical Vascular Laboratory. Founded in 1915, the Henry Ford Health System is one of the nation’s leading providers of healthcare and boasts a team of over 1,200 physicians. Their hospital is recognized for excellence in cardiology, cardiovascular surgery, and a broad spectrum of clinical specialties. The Clinical Vascular Laboratories at Henry Ford perform over 15,000 noninvasive tests annually in their state-of-the-art vascular laboratories accredited by IAC.

Cleveland Clinic Clinical Trials

In February 2018, the Company announced IRB approval by the Cleveland Clinic, sanctioning CVR to conduct clinical trials using the CSS device. The trial is to 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 U.S. 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 largest and most respected hospitals in the country.

CSS Clinical Trial Summary

Figure 25 provides a summary of current clinical trials running of the Company’s CSS system.

Figure 25
CSS CLINICAL TRIALS

Thomas Jefferson University Hospital (Philadelphia, PA)

Clinical Trial Launched:
January 2017



Primary Investigator: Dr. David Whellan MD, MHS, FACC, FAHA, Principal Investigator of Jefferson Regional Clinical Center for the NIH HF Network.

Henry Ford Hospital (Detroit, MI)

Clinical Trial Launched:
January 2017



Primary Investigator: Dr. Judith Lin MD, MBA, RVT, RPVI, Senior Staff Vascular Surgeon and Medical Director of Henry Ford’s Clinical Vascular Laboratory.

The Cleveland Clinic (Cleveland, OH)

Clinical Trial Launched:
February 2017



Primary Investigator: Dr. Heather L. Gornik, MD, MHS, MMSc., Associate Director for Vascular Trials, Medical Director of the Non-Invasive Vascular Laboratory in the Cleveland Clinic Department of Cardiovascular Medicine.

Source: CVR Medical Corp.

Market Opportunity in Primary Care Office, Specialists, and Hospitals/Clinics (Based on CVR Medical Estimates)

While the Company is initially targeting its CSS technology toward primary care physicians, there are also applications for use in emergency rooms, where specialists could use this device instead of DUS on a patient who may not need one. The majority of cardiovascular physicians have a DUS in their office. This ultrasound is performed by a certified technician, and the potential for a false positive or false negative is at a significant cost to the overall healthcare system. If there was a quicker more cost effective way to determine whether there was a blockage or not, it could save the physician not only time, but save the healthcare system money. Consequently, the CSS could prove critical not only to primary care physicians, but also cardiovascular doctors and hospitals as well.

Putting this into perspective and as illustrated in Figure 26:

- there are roughly 185,000 primary care physician offices in the U.S., where in those offices, there are approximately 900,000 physicians;
- there are 40,000 specialty offices in the cardiovascular space; and
- there are just under 10,000 hospitals and clinics.

According to CVR Medical, assuming the Company sells only one CSS device per office (which the Company believes could be on the low end), at \$49,000 per CSS device, this could become a \$9 billion potential opportunity for primary care offices; a \$2 billion opportunity for specialists' offices; and a \$480 million opportunity for hospitals/clinics. Of note is that in the U.S., 60% of primary care physician offices are owned by hospitals. Therefore, when a primary care physician receives a patient, this patient is essentially feeding the hospital's system (with DUS's, CAT's, MRI's, surgeries, etc.) Because hospitals do not want false positives and false negatives, this population of patients could be candidates for CVR Medical's technology, which the Company believes could result in increased adoption.

Figure 26
U.S. MARKET OPPORTUNITY FOR CSS (OFFICES) — COMPANY ESTIMATES

Primary Care Offices	184,845	\$49,000 (Estimated Sales Price of CSS)	\$9,057,405,000
Specialist Offices	40,000		\$1,960,000,000
Hospitals/Clinics	9,770		\$478,730,000
*Assuming only 1 device sold per office. Most offices are likely to offer multiple sale opportunities.		Total U.S. Market Opportunity	\$11,496,135,000

Source: CVR Medical Corp.



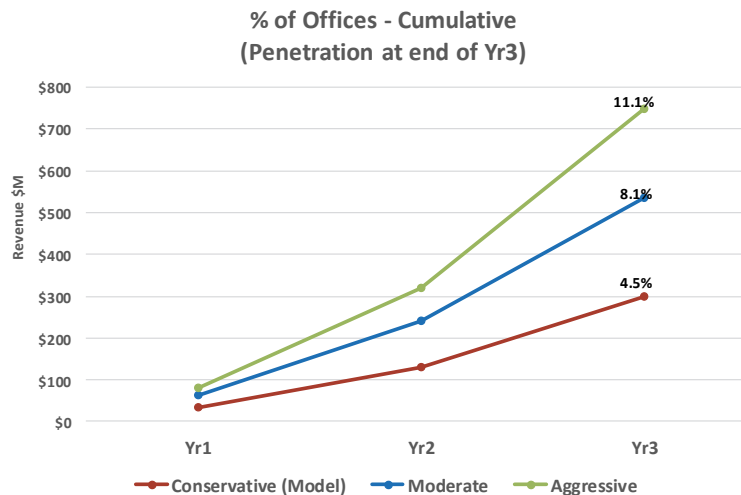
Potential Adoption in Primary Care Physician Offices (Based on CVR Medical Estimates)

Initially, CVR Medical is not anticipating having a reimbursement code, where the patient must pay for this test out of pocket at a cost of between \$100 to \$125. Patients with insurance already pay a copay or a deductible; this is essentially what the cost of the Company’s test would be (where CVR Medical believes that \$100 would be acceptable to most patients who are under either Medicare or private insurance).

Utilizing a combination of input from key market leaders and other end users, the Company has conducted market research with regard to physician adoption strategy. Approximately 200 primary care physicians were questioned whether they would use this technology in their office. Based on this questioning, the majority said they would. When questioned as to whether they would do so without reimbursement, approximately 25% said they would, while the other 75% said they were unsure. In further questioning these physicians, when recommended by a physician that a patient take the test, physician’s stated that approximately 20% patients questioned the cost of the test, where the remaining 80% of patients would take the test despite an additional cost. Of the 20% who questioned the cost of the test, 80% of patients in CVR Medical’s study stated that they would still pay for it (20% were unsure).

All indications from the Company’s research place the adoption rate somewhere between 1.75% and 3.25% of the marketplace. Based on these adoption rate estimates, the Company believes that sales of the CSS device in conjunction with its ancillary devices in the U.S. market (assuming no reimbursement) could reach \$32.6 million following initiation (Figure 27).

Figure 27
MARKET PENETRATION: SCALING POTENTIAL SCENARIOS



Source: CVR Medical Corp.

CVR Medical believes that it could have reimbursement within approximately 12 months following approval. Primary care physicians do not have other technologies akin to this in their office, other than perhaps an electrocardiogram (EKG) machine or a urinalysis. The Company believes that reimbursement could be about \$125, where the expected copayment could be in that same range (roughly \$100).

Placement in Physician's Offices

The Company has put the CSS device into select primary care offices and is screening patients in conjunction with the other indicators. If a primary physician is able to screen every patient over age 20 (which is CVR Medical's desired target), CVR Medical believes that this could serve to reduce the incidence of stroke significantly. The reason to screen at age 20 is to set up a baseline. Such screening would be preventative; thus, if a patient presents as 'at risk', this would be determined early on at the baseline testing. If they are not at risk, the patient would then be followed for the rest of his/her life (with a recorded baseline).

During their 20s, a patient may be tested once every five years; in their 30s once every three years, in their 40s once every two years, and age 50 and above, may be tested every year. Based on results from the CSS, if it is found that the patient's stenosis is increasing, decreasing, or stable—all depending on factors such as diet, exercise, smoker/nonsmoker, and medical, etc., and depending on the level of that blockage—CVR Medical's technology could provide the crucial tool for preventative care.

For example, in a patient that is 65 and asymptomatic but has a significant blockage, the device can be used for acute care determination before an event happens and, importantly, to prevent an imminent stroke. The foundation to the Company's technology is to prevent people from ever getting to that point, which is the reason for a baseline at 20 years old. Therefore, in testing every adult over age 20, the intent is to save the healthcare system a significant amount of money as patients would never get to the point of having an event. Once this is proven, CVR Medical would be able to make this claim, and the CSS would become a *screening* tool rather than a *diagnostic* tool.

A Potential Profit Center for the Physician

Once a doctor puts the device into his/her office, where it would be leased at \$1,000 per month, at \$100 per test, the doctor pays for that device in 10 days of testing one patient each of these days (noting that CVR Medical believes that this likely represents a low estimate). Primary care physicians are typically in their offices about 20 days a month. Thus, performing one test per day could potentially make \$1,000 per month in net profit (the cost of the month's lease) — $(20 \text{ days} \times \$100/\text{test}) - \$1,000 \text{ lease cost/month} = \$1,000/\text{month}$. This does not include the reimbursement, which could bring the price up to \$120 to \$125.

Importantly, the primary care doctor will likely not be running this device, but rather the medical assistant (who earns between \$10 to \$15 per hour). The test takes approximately five minutes from start to finish. Conducting roughly 100 tests per month equates to 25 tests per week. Five minute per test multiplied by 25 tests equals an hour and a half. The additional cost to that doctor's office if 20 tests per week are being conducted may be approximately \$30 in wages for that assistant's time, where the primary care's office at that point is realizing somewhere around \$100,000 in profit per year. Assuming the average primary care doctor is conducting exams on roughly 2,000 patients per year, and assuming half of these patients are over 45 years old, this would be the minimum starting point from where a diagnostic would be performed.

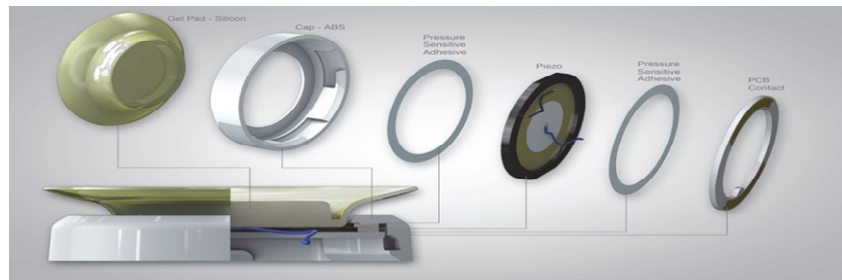
Disposable Market Opportunity (Based on CVR Medical's Estimates)

With a proposed market price of roughly \$49,000, which is significantly less expensive than alternative technologies, which can cost upwards of \$2.5 million, CVR Medical estimates that its device could generate net revenue of \$32,000 per device (Figure 28, left side). For the disposables (gel pads and sensor pods), which are used in conjunction with the device, the cost is approximately \$4.00 and CVR Medical sells them for \$18.00, accounting for a cost of sale price of \$3.60, this leaves a net profit of approximately \$10.40 per single CSS disposable (Figure 28, right side).

Figure 28

DISPOSABLE PROJECTIONS (ACCORDING TO CVR MEDICAL) — COMPANY ESTIMATES

SINGLE CSS DEVICE BREAKDOWN		SINGLE CSS - DISPOSABLE SALES POTENTIAL			
Sale Price	\$49,000	Monthly test administered per device	20	40	100
Cost of goods sold	\$10,000	Sales price per test (gel pads and sensor pod)		\$18.00	
Cost of sale	\$7,000	Cost of good sold per test (gel pads and sensor pod)		\$4.00	
Net Revenue	\$32,000	Cost of Sale		\$3.60	
Estimated lease cost: \$1,000 / month (5 years)		Net profit per test		\$10.40	
		Net profit (monthly)	\$208	\$416	\$1,040
		Net profit (yearly)	\$2,496	\$4,992	\$12,480



Note: Disposable Unit Cost of Manufacturing: Gel Pad: \$.35 Sensor Pod: \$7.00

Source: CVR Medical Corp.

Potential Expansion into International Markets

The Company has recently announced expansion into two international markets, with specifics for both China and South Korea described in the accompanying section. Additional agreements could be forthcoming as the Company's prepares for its CSS technology to reach the market. With the Chinese and the South Korean deals, there is somewhere between \$0.075 and \$0.015 per person in the population of the country as the royalty for each of these deals as additional upfront revenues, according to the Company.

China

In early January 2018, CVR Medical announced the signing of an official Letter of Intent (LOI) with Guangzhou LangRun Equity Investment Management Co., Ltd. (GLR), a professional equity investment fund management platform company headquartered in Guangzhou, China, who plans to create the "LangRun Asset Fund" to focus on investment in medical devices specific to senior care and healthcare optimization. The idea behind this LOI is for it to fund a proposed 35% (CVR)/65% (GLR) JV to market, and assemble and distribute CVR Medical's CSS device throughout Mainland China. The LOI puts CVR Medical in a position to achieve its goal of expanding into the Asian-Pacific market upon product launch and sets the trajectory for a target launch release into the Chinese market in 2019. Currently, China and India are the most populated countries in this Asian-Pacific region, with China being the second largest economy and home to the world's largest population—with close to 1.38 billion people.

South Korea

Also in early January 2018, CVR Medical announced the signing of an official Memorandum of Understanding (MOU) with the Seoul Metropolitan Government (SMG) of the Republic of South Korea. The MOU states the mutual interest and intended collaboration on new business opportunities as part of CVR Medical's global market expansion and the South Korean government's initiative to revitalize its bio-medical device industry. Through its partnership with the SMG, CVR Medical expects to be positioned to take advantage of a vast and growing Asian-Pacific market while leveraging Seoul's financial, administrative, and R&D capacities upon launch of the CSS.

Manufacturing

Canon U.S.A. Contract

CVR Medical is transitioning from being a research company—undergoing clinical trials—into a full scale medical device sales and marketing company. The Company currently has a contract in place with Canon U.S.A. to build and manufacture its devices, where Canon will completely house the product and 'white glove' deliver it to the doctor's office subsequent to its sale. CVR Medical intends to employ an external sales teams, such as been done by other medical device companies, with no intention of building an internal sales team. An overview of the LOI with Canon is provided in Figure 29.

Figure 29

MANUFACTURING PARTNERSHIP WITH CANON U.S.A. (LOI EXECUTED JULY 2017)



- Canon's global supplier and distributor relationship is expected to expedite speed to market while decreasing cost
- Mutually beneficial financial terms
- 2 million sq ft. facility to house CSS manufacturing
- Legal manufacturer of Carotid Stenotic Scan (CSS)
- Engineering
- Assembly
- Logistics/supply chain management
- Service/customer service/warranty
- Reduced to-market resource requirements

Source: CVR Medical Corp.

Subsequent to the delivery of the device, Canon will provide the necessary technical support and service. If it becomes necessary to service, Canon will send the doctor a replacement machine, which will come in a shipping crate and the old device will be shipped back to Canon. In an effort to build a positive experience for doctors, CVR Medical intends to make this a very easy and seamless experience for the doctor’s offices.

Typically for a medical device company, the biggest risk is in the manufacturing process, which can be very capital expense-oriented. Since Canon is taking over the supply chain, with a dedicated space, this represents a significant part of the value of what Canon is investing into CVR Medical—equivalent to upwards of \$20 million of paid in capital. Since Canon will be manufacturing the device, they oversee creation of all the molds and extrusions, as well as all of the components that go into this device. As well, Canon is buying all the supplies and components from the suppliers that manufacture those components.

CVR Medical believes that it could gain a significant lead out of the box given the relationship with Canon and the fact that they have invested the time to ensure the quality of the product and technology associated with it. Physicians are aware of Canon and its reputation for not only delivering a quality product but also for being able to provide any technical support that is needed. Furthermore, Canon provides CVR Medical with the ability to scale up production, whether to 100,000 or 1,000,000 units per year.

Canon Virginia, Inc. (CVI)

Figure 30
 CANON VIRGINIA, INC. (CVI) SHOWCASING CSS AT
 NPE 2018: THE PLASTICS SHOW, THE WORLD’S LEADING
 PLASTIC TRADESHOW



Source: CVR Medical Corp.

In early January 2018, CVR Medical announced the signing of a manufacturing agreement with Canon Virginia, Inc. (CVI), a manufacturing, engineering, and technical operation for Canon and a wholly-owned subsidiary of Canon U.S.A. From their state-of-the-art facility in Newport News, Virginia, CVI is a leading global manufacturer of high tech consumer goods since 1985, and has recently expanded its scope to include ISO 13485 certification and a new facility dedicated to advanced medical device manufacturing.

This recent agreement finalizes Canon Virginia’s status as primary manufacturer, assembler, and logistical authority, as well as technical support for CVR Medical’s CSS device. Canon’s extensiveness of in-house capabilities and supply-chain efficiencies could translate into millions of dollars in short-term production and logistical cost savings for CVR Medical. As well, the Canon’s reputation is likely to afford the Company’s technology instant brand recognition among doctors to put CVR Medical on a course to change the cardiovascular healthcare landscape.

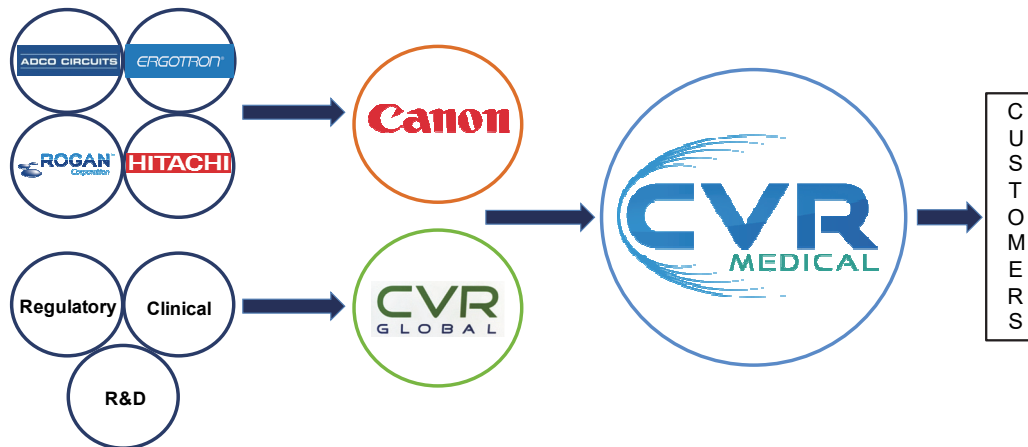
In early May 2018, Canon Virginia, Inc. (CVI) showcased the Company’s CSS product at NPE 2018: The Plastics Show, the world’s leading plastic tradeshow (Figure 30). NPE Participants included buying teams from over 100 countries and more than 20,000 companies comprising the entire

global plastics supply chain. Furthermore, this tradeshow draws over 2,000 exhibiting companies, 65,000 manufacturing representatives from every segment of the plastic industry and its vertical markets including, medical devices and supplies, automotive, building and construction, and packaging and consumer products.

Key Suppliers

Figure 31 provides an overview of the Company’s suppliers, along with brief descriptions of select arrangements. Canon is taking on accounts with all of the suppliers, as described in the accompanying section, where each supplier will be working directly with Canon. Importantly, these suppliers are required to have strong quality and regulatory systems, as well as the ability to scale rapidly.

Figure 31
KEY SUPPLIERS



Source: CVR Medical Corp.

Rogan Molding Technologies

CVR Medical announced a partnership with Rogan Molding Technologies of Northbrook, Illinois to be the exclusive manufacturer of the patient-interfacing gel pad for the CSS. Rogan Molding Technologies is a staple organization in original equipment manufacturing (OEM) and a global leader in the injection molding industry. Being ISO 9001 and 13485 certified, their cleanroom facilities are anticipated to meet the highly specialized needs of CVR Medical’s CSS device and the accompanying gel pads.

ADCO Circuits

CVR Medical also has a partnership with ADCO Circuits, a Michigan-based electronic design and manufacturing company, in which ADCO is to be the exclusive provider of the custom circuit board inside the sensor of the Company’s CSS device. ADCO Circuits is a certified ISO 9002, ISO AS9100, and ISO TS16949 manufacturer of electronic assemblies and full system box builds and is recognized as an industry leader capable of managing projects from prototype to volume production. ADCO’s state-of-the-art manufacturing facility is intended to enable maximum efficiency in the full-scaled production process.

Hitachi High Technologies America, Inc. (HTA)

Hitachi High Technologies America (HTA) is developing and creating the processing unit to operate the CSS device. The processor HTA has designed enables the CSS to interpret the sub-sonic and infrasonic sound waves it intakes, and allows for the results to be displayed on a monitor in real time.



Joint Venture: CVR Medical Corp. and CVR Global Inc.

CVR Medical Corp's predecessor was Big Bar Resources Corporation. On September 23, 2016, Big Bar Resources Corporation successfully initiated a change of business, transitioning to a medical technology company after forming a joint venture with CVR Global, Inc., (CVR Global) with a subsequent name change to CVR Medical Corp. On September 16, 2016, CVR Medical bought the patents of a medical device known as Carotid Stenotic Scan (CSS) developed by CVR Global.

In order to commercialize the device, the Company and CVR Global entered into an equal part equity joint venture. Under this joint venture arrangement, CVR Medical would offer patents, working capital, investor relations, and global market rights. CVR Global's role would be to provide additional patents, management know-how, and intellectual property of the device and market expertise. In March 2017, CVR Medical announced in a Letter of Intent that it was interested in acquiring an additional 10% interest in the existing 50%/50% JV with CVR Medical thereby proposing to increase its stake to 60%. To date, CVR Medical has operated under the original 50/50 JV as both parties continued to negotiate in good faith. CVR Medical determined that a more conventional agreement seen in other medical device companies should be considered and adopted.

On May 29 2018, CVR Medical Corp. announced that it has reached agreement with joint venture partner CVR Global to acquire CVR Global's 50% interest in the joint venture and terminate the joint venture. The Agreement has been approved by the Board of Directors for both organizations and is now subject to the approval of CVR Medical's shareholders and (inclusive of all proposed share issuances) the TSX Venture Exchange.

For CVR Medical and CVR Global, the potential move is one of mutual benefit. Upon consultation with bankers, attorneys, and stakeholders, both companies recognized that this conventional milestone driven equity distribution and royalty structure significantly strengthens the business model of CVR Medical ahead of the release of its CSS device. The move from the joint venture partnership (which has served both companies effectively to this point) to this next structural phase, is a signal of confidence that CVR Medical is in position to successfully control the finalization of development and transition into marketing and sales of the CSS.

The deal, as currently structured, requires CVR Global to relinquish its rights to share profits from the sale of the CSS by dissolving the joint venture, but allows for its continued sharing of risk and reward through CVR Medical with the issuance of 30 million additional shares to be released to CVR Global upon successfully achieving four milestones. The deal will also leverage CVR Global's R&D efforts to include any improvements on all future medical devices related to CVR Medical's existing field of use, Carotid Arterial Health (Stroke), as well as improvements to any and all related IP. Upon completion of all mutually agreed to milestones, this sharing of risk is expected to result in CVR Global becoming CVR Medical's largest individual shareholder.

The proposed distribution of the CVR Medical shares would include:

- 3 million shares issued upon signing of the agreement;
- 2 million shares issued upon FDA submission;
- 10 million shares issued upon achieving FDA clearance/approval; and
- 15 million shares issued upon achieving \$50 million in revenue from the sales of the CSS, contingent on a maximum 36-month timetable after its initial sale.

Additionally, CVR Global would also be granted a 7% royalty on all device sales, as well as 3% royalty on all disposable sales. Upon completion of all milestones and stock issuance, CVR Global will become CVR Medical's largest stakeholder.

Financial Status

To date, CVR has raised approximately C\$24.5 million via four separate rounds of equity financings and a warrant price reduction. The Company's on-going pivotal clinical trials, pre-FDA submission, and other pre-market launch activities require its monthly burn rate to approach C\$650,000. The Company has retained Wall Street Investment Banking firm, Think-Equity, to explore a U.S. National Markets Listing as well as assist in raising capital to fund its ongoing operations utilizing the capital markets via private placements and other forms of equity, which would be in compliance with the TSX Venture Exchange pricing regulations. NYC-based Think-Equity, is a boutique investment bank created by professionals that have worked together for over a decade, collectively financing over \$50 billion of public and private capital raises, restructuring, and merger and acquisitions. Figure 32 provides a snapshot of the Company's current capitalization structure.

Figure 32
CAPITALIZATION TABLE

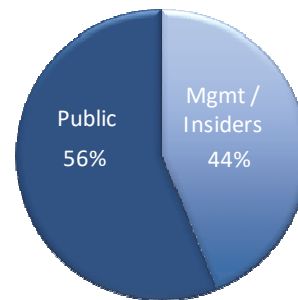
Exchange Listings: TSXV:CVM / OTCQK:CRRV.F
LSE:0UMW / DB:B3BN

Share Price: C ~\$0.355

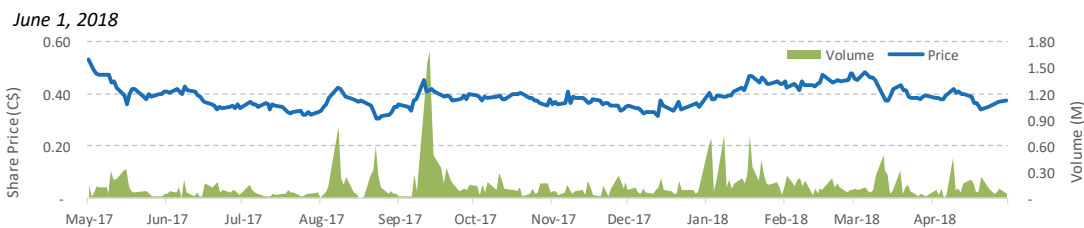
52-Week Range: C\$0.28 - C\$0.58

Market Cap: C\$26.2 million

Avg Volume (30D): 64,833



Shares (M)	
Basic	100.9
Options	4.1 <i>W.Avg C\$0.22/sh and 3.4 yrs</i>
Warrants	16.8 <i>W.Avg C\$0.44/sh and 0.7 yrs</i>
Fully Diluted	121.8



Source: CVR Medical Corp.

Investment Highlights

- CVR Medical Corp. (“CVR Medical” or “the Company”) is a medical technology company dedicated to developing and commercializing a revolutionary device within the healthcare sector to assess carotid arterial health in a primary care physician’s office in order to quickly and cost-effectively identify patients at risk for stroke and enable early intervention.
 - Stroke is a serious medical condition that requires immediate emergency care as it can cause lasting brain damage, long-term disability, or death. As the fifth leading cause of death in the U.S., stroke results in one of 20 adult deaths, at cost of roughly \$34 billion per year, with many of these deaths possibly preventable. While cardiac disease is the primary cause of death, stroke is the leading cause of long-term disability (50% of victims are permanently impaired).
- The Company’s innovative Carotid Stenotic Scan (CSS) device uses low frequency sound wave analysis to detect and measure carotid arterial stenosis (narrowing of the blood vessels in the neck that carries blood from the heart to the brain) or occlusion (the blockage or closing of a blood vessel or hollow organ), which are the leading risk factors for stroke.
- The stroke diagnostic market is currently devoid of cost-effective tools that primary care physicians and other healthcare providers can use to initially diagnose a patient’s risk of stroke prior to any symptoms or incidence. CVR Medical’s technology has been developed to address this void as its CSS device can be performed in a primary care physician’s office, is non-emissive (does not use harmful radiation to obtain a result), non-invasive, does not require a certified technician, and can be conducted within a few minutes.
 - CSS requires only a small footprint, and has a price per scan and cost requirement that is significantly lower than alternative stroke diagnostic technologies. With a proposed market price of \$49,000, CSS is significantly less expensive than current diagnostic alternatives currently used to determine arterial health—including duplex Doppler ultrasound (DUS), magnetic resonance angiography (MRA), and computed tomography angiography (CTA)—which are priced as high as \$2.5 million per device.
- The CSS device is undergoing pivotal trials at several world-renowned medical institutions. These trials play a crucial role in accelerating substantiation for the CSS and shortening the FDA submission timeline for approval.
 - The Company’s CSS technology is being evaluated at Thomas Jefferson University Hospital in Philadelphia through the ENTICES (Evaluation of a Novel Technique to Investigate CAS piezo-Electric Sensors) Study, to evaluate CSS against current ultrasound technologies. Following promising results, Thomas Jefferson University Hospital is expected to begin pivotal trials imminently.
 - Another clinical trial at the Henry Ford Hospital in Detroit is underway. One device has been fully deployed, with two additional scheduled for the coming weeks.
 - In February 2018, the Company announced IRB approval by the Cleveland Clinic, sanctioning CVR to conduct clinical trials using the CSS device.
- CVR Medical is transitioning from being a research company—undergoing clinical trials—into a full scale medical device sales and marketing company. The Company currently has a contract with Canon U.S.A., where Canon will manufacture, assemble, service, and ‘white glove’ deliver the CSS to a doctor’s office. Canon brings significant value to the Company as it has a dedicated space with the ability to rapidly scale production.
- CVR Medical has strong intellectual property (IP) position, including one issued patent, 13 patents pending, and over 20 patents under process, providing high barriers to entry, with significant IP surrounding its CSS.
- The Company’s executive team consists of veterans from the medical device industry with business acumen from key areas in healthcare.

Note: All amounts cited in this section are in U.S. dollars unless noted otherwise.

Competition

CVR Medical is working toward commercializing a disruptive proprietary low frequency sound wave analysis technology—Carotid Stenotic Scan (CSS)—to diagnose the risk of stroke at the primary physician level. The Company believes that the stroke diagnostic market currently lacks the cost-effective tools to easily diagnose the risk of a stroke and to assess the health of carotid arteries by the primary healthcare provider.

As CVR Medical seeks to develop and market its proprietary technology, it may encounter competition from companies developing new technologies in the stroke diagnostic space, as well as established participants, including those companies that market the technologies currently used as the standard of care, such as CTA, MRI, DUS, cerebral angiography, electrocardiography, and echocardiography (as described on pages 21-23).

The Company believes that its CSS technology provides significant advantages over the current standard of care in terms of cost, operation, time, and patient experience. The CSS device is cost effective when compared to other arterial diagnostic devices capable of achieving the same results. With a proposed market price of roughly \$49,000, this compares favorably to alternative technologies, which can cost as much as \$2.5 million and require large spaces to operate. In addition, CSS is non-invasive, requires no licensed personnel to operate, and requires no need for interpretation of results by medical specialists. Furthermore, the CSS device is a non-emitting medical device requiring significantly less scan test time than other devices. Figure 33 summarizes key competitive advantages of the Company’s CSS technology compared to the most common diagnostic alternatives.

Figure 33
CSS COMPETITIVE COMPARISON

	Carotid Stenotic Scan (CSS)	Carotid Doppler Ultrasound	Magnetic Resonance Angiography	Computed Tomography Angiography
Cost	\$49,000	\$250,000	\$1 million-\$2.5 million	\$1 million-\$2.5 million
Certified Tech Required	NO	YES	YES	YES
Fee	\$*	\$\$\$	\$\$\$\$	\$\$\$\$
Reimbursement	105*	\$180-\$400	\$3,000	\$500-\$1,500
Non-emitting Technology	YES	NO	NO	NO
Non-invasive Technology	YES	YES	NO	NO
Accurate and Repeatable	YES	NO	NO	NO
Scan Time	2 minutes	30-60 minutes process	> 60 minutes process	30-60 minutes process

* Estimated amounts

Source: CVR Medical Corp.

Key participants operating within the global stroke diagnostics and therapeutics market include Abbott Laboratories, Boston Scientific Corporation, Cordis Corporation (Johnson & Johnson), Covidien plc, GE Healthcare, Genentech, Inc., Hitachi, Ltd., Koninklijke Philips N.V., Medtronic plc, Merck & Co., Inc., Penumbra, Inc., Siemens AG, and Stryker Corporation (Concentric Medical, Inc.); with some of the leading participants developing new technologies in the ischemic stroke diagnosis market, as described on the accompanying pages. The following section is not intended to be an exhaustive collection of potential competitors to the Company, but rather, it is believed to be representative of the type of competition that CVR Medical may encounter as it seeks to further develop and commercialize its technology.

AliveCor, Inc.

AliveCor is a medical device company involved in the creation of a mobile electrocardiogram (ECG) technology to enable proactive heart care. The FDA-cleared Kardia Mobile app is the first artificial intelligence (A.I.)-enabled mobile ECG platform on the market. This simple-to-use app-based service—when paired with its standalone EKG reader devices KardiaMobile or KardiaBand (the first FDA-cleared medical device accessory for the Apple Watch®)—provides instant analysis for the early detection of atrial fibrillation (AF) and normal sinus rhythm. In addition, the company released Kardia Pro, the first A.I.-enabled stroke prevention platform for doctors to monitor patients for the early detection of atrial fibrillation, the most common cardiac arrhythmia that leads to a five times greater risk of stroke. The Kardia Pro platform was built following a partnership with the Mayo Clinic that included a major study on stroke involving 4,500 patients. The Kardia Pro tracks a number of factors for at-risk patients, and the company's A.I. technology can point to potential triggers doctors may not detect on their own, allowing physicians to monitor patients who may be at risk for stroke or other heart-related diseases. AliveCor is a privately-held company headquartered in Mountain View, California.

Forest Devices, Inc.

Forest Devices is a clinical-stage medical device company developing a portable stroke-screening technology, AlphaStroke, the first device designed to be used by medical personnel to detect stroke in any environment. Acting like an EKG for the brain, AlphaStroke aims to allow pre-hospital providers the ability to determine if the patient is having a stroke. On January 2018, Forest announced it had successfully closed a seed round of \$2.3 million to be used to carry out a large multi-site clinical trial, further research and development, and business development activities. Forest Devices was founded in 2015 and is headquartered in Pittsburgh, Pennsylvania.

GE Healthcare

GE Healthcare, the healthcare business of General Electric Corporation, is a leading provider of medical imaging equipment, with a track record of more than 100 years in the industry and more than 50,000 employees across 100 countries. In addition to its imaging solutions, the company offers software solutions to assist in the analysis and visualization of the images. GE Healthcare's Stroke VCAR (Volume Computer Assisted Reading) provides a simplified workflow solution to help analyze and assess intracerebral and subdural hematomas aneurysms. Furthermore, on November 2017, the company announced a partnership with MedyMatch Technology to integrate MedyMatch's A.I.-based software to help clinicians assess head trauma or stroke using its imaging solutions. Working with GE Healthcare, MedyMatch plans to integrate its intracranial hemorrhage detection platform into GE's CT imaging solutions in order to help clinicians in their assessment of patients suspected of having acute head trauma or stroke.

Jan Medical, Inc.

Jan Medical is a medical device start-up dedicated to accelerating therapy while improving the diagnostic experience for patients with brain disorders. Jan Medical is developing BrainPulse™, a diagnostic tool designed to rapidly and reliably help detect abnormal neurological conditions, including concussion and stroke. The BrainPulse™ system, which consists of a headset, data collector, and computer, captures a novel, non-invasive, physiological signal that utilizes the cardiac output to measure vasculature and brain tissue conditions. The system then uses that data to provide a clinically relevant 'aid to diagnoses' for a range of indications, including concussion and stroke. A typical recording takes only three to five minutes, and can be done by physicians, nurses, athletic trainers, or other medically trained personnel in a variety of athletic, military, or hospital settings. The BrainPulse™ has received *de novo* clearance from the FDA as a Class II device for cranial motion measurement, with the company actively pursuing the development of algorithms for concussions and stroke detection. Jan Medical is headquartered in Mountain View, California.

MedyMatch Technology, Ltd.

MedyMatch is a medical A.I. company delivering a real-time clinical decision support platform to improve patient outcomes in acute medical scenarios. The company's technology can be integrated into healthcare systems, including medical imaging hardware, to deliver precise clinical decision support directly to the physician at the patient's bedside. MedyMatch's lead application is an AI-based software to help clinicians and emergency room imaging experts correctly diagnose head trauma or stroke. When a patient undergoes a head CT scan, MedyMatch's platform analyzes the image and data to assess where there may be bleeding. MedyMatch aims to distribute its technology through partnerships with healthcare and technology companies, including agreements with GE Healthcare and Samsung Neurologica Corporation to integrate its platforms into their medical imaging products, as well as IBM. Through the later partnership, IBM Health Watson Imaging group is planning to distribute MedyMatch's brain bleed detection application globally through its vendor neutral sales channels, while the two companies expect to develop interoperability between the products and services. MedyMatch is based in Tel Aviv, Israel.

Samsung Neurologica Corporation

Samsung's NeuroLogica, the healthcare unit of Samsung Electronics Co., Ltd, develops, manufactures, and markets innovative imaging and advanced medical technologies, including CT scans, digital radiography, and ultrasound systems. On March 2017, Samsung announced a collaboration with MedyMatch Technology Ltd., to integrate the Israeli startup's A.I.-based decision software with Samsung's medical imaging machines in prehospital settings for emergency use. The first area of focus will be strokes, whereby MedyMatch technologies will be integrated into mobile stroke units (MSU), specialized ambulances or other emergency vehicles that are equipped with a Samsung CT scanner. The combined system allows a medical team to quickly assess whether a patient is having a brain bleed and whether the stroke is caused by a blood clot or hemorrhage. The assessment allows caregivers to quickly perform the most appropriate treatment path, even while in transit to the hospital. The company is headquartered in Danvers, Massachusetts.

Sarissa Biomedical Ltd

Sarissa specializes in the development and production of novel biosensors for the measurement of neuroactive chemicals during in vitro and in vivo studies for research and clinical diagnostic applications. Sarissa offers a range of minimally invasive, microelectrode electrochemical sensors for the measurement of the purines (a key and very early biomarker of hemorrhagic, ischemic, and inflammatory injuries) and other neurochemicals, as indicators of neurological activity/disorders, from finger prick samples of blood within minutes. The company is developing a stroke diagnostic technology, SMARTChip, which provides clinicians and paramedics with the physiological information to compliment clinical assessment at the point-of-care. Sarissa is headquartered in Coventry, England.



Historical Financial Results

Figures 34, 35, and 36 (pages 44-46) provide a summary of CVR Medical's key historical interim financial statements for the quarter ended March 31, 2018, noting all amounts are reported in Canadian dollars (C\$).

Figure 34

INTERIM STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited — Prepared by Management)
(Expressed in Canadian dollars)

	Three Months Ended	
	March 31,	
	2018	2017
	\$	\$
Expenses		
Depreciation	78	39
Consulting fees	115,942	469,119
Interest	44	218
Foreign exchange loss	5,174	10,832
Office and general	184,588	390,743
Professional fees	26,249	21,707
Rent	4,200	5,900
Share-based compensation	—	221,170
Travel and entertainment	29,923	44,236
Transfer agent and filing fees	25,790	31,511
Research and development costs	680,804	908,618
Loss before other income	(1,072,792)	(2,104,093)
Other income (expense)		
Write-off of advance to CVR Global, Inc.	(683,333)	(1,098,328)
Net and comprehensive loss	(1,756,125)	(3,202,421)
Loss per share – basic and diluted	(0.03)	(0.07)
Weighted average number of shares outstanding	65,741,309	45,522,677

Source: CVR Medical Corp.

Figure 35
 INTERIM STATEMENTS OF FINANCIAL POSITION
 (Unaudited — Prepared by Management)
 (Expressed in Canadian Dollars)

	March 31, 2018	March 31, 2017
	\$	\$
Assets		
Current		
Cash and cash equivalents	121,199	582,764
Prepaid expenses	92,055	72,974
Sales tax recoverable	50,162	39,525
Total Current Assets	263,416	695,263
Equipment	1,203	1,281
Intangible assets	1,470,000	1,470,000
Total Assets	1,734,619	2,166,544
Liabilities and Shareholders' Equity		
Liabilities		
Current		
Accounts payable	48,004	16,424
Accrued liabilities	12,000	20,000
Due to related parties	92,418	99,867
Total Liabilities	152,422	136,291
Shareholders' Equity		
Share capital	22,817,830	21,515,696
Option reserve	2,182,616	2,176,681
Deficit	(23,418,249)	(21,662,124)
Total Shareholders' Equity	1,582,197	2,030,253
Total Liabilities and Shareholders' Equity	1,734,619	2,166,544

Source: CVR Medical Corp.



Figure 36
 INTERIM STATEMENTS OF CASH FLOWS
 (Unaudited — Prepared by Management)
 (Expressed in Canadian dollars)

	Three Months Ended	
	March 31,	
	2018	2017
	\$	\$
Cash (used in) provided by:		
Operating activities		
Net loss	(1,756,125)	(3,202,421)
Items not involving cash:		
Depreciation	78	39
Share-based compensation	—	221,170
Write-off of advance to CVR Global, Inc.	683,333	1,098,382
Net changes in non-cash working capital items:		
Sales tax recoverable	(10,637)	(8,535)
Prepaid expenses	(19,081)	7,961
Accounts payable	31,580	(55,602)
Accrued liabilities	(8,000)	(10,235)
Due to related parties	(7,449)	(10,750)
Net cash used in operating activities	(1,086,301)	(1,960,045)
Cash flows from financing activities		
Deferred financing costs	—	(18,543)
Shares subscriptions received	—	205,200
Shares issued for exercise of stock options	—	257,250
Shares issued for exercise of warrants	104,762	696,006
Shares issued for cash, net of issuance costs	1,203,307	2,385,567
Net cash provided by financing activities	1,308,069	3,525,480
Cash flows from investing activities		
Advance to CVR Global, Inc	(683,333)	(1,098,328)
Purchase of equipment	—	(1,553)
Net cash used in investing activities	(683,333)	(1,099,881)
Decrease (Increase) in cash and cash equivalents	(461,565)	465,554
Cash and cash equivalents, beginning of period	582,764	131,232
Cash and cash equivalents, ending of period	121,199	596,786
Supplemental disclosures:		
Interest paid	—	—
Income tax paid	—	—
Non-cash investing and financing activities:		
Shares issued for patents	—	—
Fair value of brokers warrants for share issuance costs	5,935	—

Source: CVR Medical Corp.

Recent Events

05/29/2018—CVR Medical Corp. announced that it has reached agreement with joint venture partner CVR Global to acquire CVR Global's 50% interest in the joint venture and terminate the joint venture. The Agreement has been approved by the Board of Directors for both organizations and is now subject to the approval of CVR Medical's shareholders and (inclusive of all proposed share issuances) the TSX Venture Exchange.

05/22/2018—Announced it has retained BUYINS.NET, a provider of Regulation SHO compliance monitoring, short sale trading statistics, and market integrity surveillance to initiate coverage on CVR Medical after releasing the latest short sale data through May 17, 2018.

05/10/2018—Announced Colonel Dallas C. Hack, MD, MPH, MSS, FACMPH, FS, CPE has been unanimously appointed to the Company's Board of Directors, replacing Mr. Erwin Wong who is retiring. Colonel Hack is a brain injury expert and is board certified in Preventive Medicine with multiple degrees and certifications, including a Master of Public Health and a Master of Strategic Studies. Colonel Hack will also serve on the Company's Medical Advisory Board as the Company moves toward market entry of its CSS device.

05/09/2018—Announced the receipt of official meeting minutes for the Pre-Submission meeting on March 23, 2018 with the U.S. Food and Drug Administration (FDA) regarding the CSS device and its upcoming FDA submission for market release. Attendees of the meeting included CVR management, regulatory consultants Duval & Associates, and key reviewers from the FDA. The purpose of the meeting was to receive feedback and define the necessary regulatory pathway, clinical trial substantiation requirements, and device testing. Based on prior communication with the FDA and input provided by key regulatory advisors, CVR had considered the potential for either a 510(k), *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 that 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.

05/07/2018—Announced that Canon Virginia, Inc. (CVI) will be showcasing CVR Medical's CSS at NPE 2018: The Plastics Show, the world's leading plastic tradeshow. CVI, a wholly owned subsidiary of Canon U.S.A., Inc., provides custom manufacturing solutions, including mold making, injection molding, medical contract manufacturing, and automated assembly capabilities. NPE participants includes buying teams from over 100 countries and more than 20,000 companies comprising the entire global plastics supply chain. NPE draws over 2,000 exhibiting companies, 65,000 manufacturing representatives from every segment of the plastic industry and its vertical markets including, medical devices and supplies, automotive, building and construction, packaging, and consumer products.

05/03/2018—Announced that the Company has appointed Mr. Tom J. Harris to the position of Chief Financial Officer (CFO). Replacing Mr. Erwin Wong, who is retiring from his position as CFO, Tom J. Harris will spearhead fiscal preparations while contributing to overall organizational expansions as CVR continues its shift from research and development to a sales and marketing focus for the upcoming launch of their flagship medical device CSS.

05/01/2018—Announced the addition of Mr. Wayne Hellman to its Board of Directors and appointment as Vice-Chairman. Mr. Hellman will assume an active role focused on the continued development and upcoming launch of CVR Medical's CSS.

04/16/2018—Announced that the Company intended to complete a private placement financing for gross proceeds of up to \$1,000,000, which is expected to consist of units, with each unit comprised of one common share and one-half of one common share purchase warrant at a price of \$0.40 per unit, or such other price per unit determined by CVR Medical management in compliance with TSX Venture Exchange pricing regulations. Each whole share purchase warrant will be exercisable to acquire one common share of CVR Medical at a price of \$0.70 per share for a period of twelve months following the closing of the financing. The financing is non-brokered. CVR Medical intends to pay finder's fees of up to 6% in cash and 6% in warrants in connection with the financing. Proceeds from the financing are expected to be used for ongoing working capital requirements relating to a joint venture, specifically with regard to FDA applications and clinical trials. Completion of the financing is subject to Exchange acceptance, and all securities issued pursuant to the financing will be subject to a hold period of four months as required under applicable securities legislation.

04/10/2018—Announced that the temporary warrant exercise price amendment expired at the close of business on April 6, 2018. An aggregate of 2,518,600 warrants originally issued in the February and April 2017 private placements were exercised for gross proceeds of \$1,007,440. CVR Medical also issued a total of 2,518,600 new warrants to those holders that exercised their 2017 Warrants. The New Warrants have an exercise price of \$1.50 and will expire on April 9, 2020. In the Amendment closing, CVR Medical paid finders' fees of 5% cash, comprised of an aggregate cash commission of \$22,811.14. The New Warrants and any common shares issued upon the exercise of the New Warrants are subject to a hold period expiring on August 10, 2018. The Amendment remains subject to final acceptance of the TSX Venture Exchange.

03/19/2018—Announced that it will temporarily reduce the exercise price of its outstanding 2017 warrants originally issued in February and April 2017 from CAD \$0.70 to CAD \$0.40 for the period commencing on March 16, 2018 and ending at the close of business on April 6, 2018. Holders who exercise any or all of their 2017 Warrants during the Designated Exercise Period will receive one additional newly issued warrant for each 2017 Warrant exercised. The New Warrants will be exercisable at a price of \$1.50 for a period of 24 months from their issuance.

03/13/2018—Announced placement of two additional wireless CSS devices into clinical trials at historic Methodist Hospital, part of the Thomas Jefferson University Hospital System. This deployment will be combined with the three wireless CSS devices already in use across the Thomas Jefferson University Hospital footprint. This critical milestone will assist in increasing the volume of clinical substantiation data to be used in the upcoming FDA submission to acquire market clearance.

03/07/2018—Announced that advisory staff member Dr. Phillip J. Bendick, PhD, has completed his second clinical report summarizing additional data collected from tertiary clinical trials for the CSS device. His report confirms the evaluation stated in the prior report, issued in September 2017, which predicted improved accuracy in the ability to identify the narrowing of arteries. Within the upper and lower ranges of acceptable data, as defined by the improved software, the CSS concurred with Duplex Doppler Ultrasound 235 times out of 295 total tests (lower threshold) and 255 times out of 263 (upper threshold).

02/27/2018—Announced Internal Review Board (IRB) approval by the Cleveland Clinic, sanctioning CVR to conduct clinical trials using the 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.

02/20/2018—Announced the launch of pivotal clinical trials beginning Monday March 5, 2018 for the CSS device. This anticipated milestone represents the final phase of clinical substantiation which CVR will use to support the upcoming FDA submission. Initially, Thomas Jefferson University Hospital (Philadelphia, PA) and Henry Ford Hospital (Detroit, MI) will act as the key pivotal trials locations, but CVR plans to expand the footprint as other locations come online, increasing the speed of data procurement and shortening the timeframe to submission.

02/08/2018—Announced that CVR Medical has joined Canon Virginia, Inc. (CVI) at PLASTEC West (February 6-8, 2018), the largest domestic conference and expo for advanced design and manufacturing of plastics technologies. CVI, subsidiary of Canon U.S.A., Inc., is the sole manufacturer of the cart for CVR Medical's CSS device.

02/06/2018—Announced the placement of an initial order of touch panel PC’s for its CSS device. This order represents the preliminary inventory build necessary for an FDA submission and subsequent market launch. Hitachi High Technologies America, Inc. (“HTA”) designed the unique core processor for the CSS, which CVR Medical believes will enable the CSS to interpret the sub-sonic and infrasonic sound waves it intakes and display results in real time. It is one of the unique, signature elements of the device that is aiming to revolutionize preventative testing of carotid artery stenosis.

02/01/2018—Announced the launch of the Pre-Pivotal Trial clinical substantiation phase for the CSS device. This critical stage, prior to launch of final phase Pivotal Trials, will be conducted at Thomas Jefferson University Hospital (Philadelphia, PA), Henry Ford Hospital (Detroit, MI), and several other top-tier clinical research institutions within the U.S.

01/31/2018—Announced that it intends to complete a private placement financing for gross proceeds of up to \$2,000,000. The financing is expected to consist of units, with each unit comprised of one common share and one-half of one common share purchase warrant at a price of \$0.40 per unit, or such other price per unit determined by CVR Medical management in compliance with TSX Venture Exchange pricing regulations. Each whole share purchase warrant will be exercisable to acquire one common share of CVR Medical at a price of \$0.70 per share for a period of twelve months following the closing of the Financing.

01/23/2018—Announced the commencement of clinical data acquisition by the CSS device at the renowned Henry Ford Hospital. There is currently one wireless CSS device fully deployed within the Henry Ford system, with two additional devices slated for implementation in the subsequent weeks. This clinical trial plays a crucial role in accelerating clinical substantiation for the CSS device and shortening the timeline for CVR Medical’s imminent FDA submission.

01/18/2018—Investment Inventory Regulatory Organization of Canada (IIROC) has requested CVR Medical to re-state its press release entitled “CVR Medical Enters China, Executes Preliminary LOI to Launch Its CSS Device in World’s Largest Market” dated January 17, 2018 with increased specificity with regard to the LOI between CVR Medical and Guangzhou LangRun Equity Investment Management Co., Ltd. (GLR).

01/17/2018—Announced the signing of an official Letter of Intent with GLR, a professional equity investment fund management platform company headquartered in Guangzhou, China. GLR plans to create the “LangRun Asset Fund” focused on investment in medical devices specific to senior care and healthcare optimization, and which will fund a proposed 35% (CVR)/65% (GLR) joint venture to market, assemble, and distribute CVR Medical’s patented CSS device throughout Mainland China.

01/11/2018—Announced the signing of an official Memorandum of Understanding (MOU) with the Seoul Metropolitan Government (SMG) of the Republic of South Korea. The Understanding states the mutual interest and intended collaboration on new business opportunities as part of CVR Medical’s global market expansion and the South Korean government’s initiative to revitalize its bio-medical device industry.

01/09/2018—Announced IRB approval of clinical trials for its CSS device at Michigan’s Henry Ford Hospital. The trials will be overseen by Judith Lin, MD, MBA, RVT, RPVI, Senior Staff Vascular Surgeon and Medical Director of Henry Ford’s Clinical Vascular Laboratory.

01/02/2018—Announced the signing of a manufacturing agreement with Canon Virginia, Inc. (CVI), a manufacturing, engineering and technical operation for Canon and a wholly-owned subsidiary of Canon U.S.A. The agreement finalizes CVI’s status as primary manufacturer, assembler, and logistical authority for CVR Medical’s CSS device. The Company’s novel device, currently undergoing final phase trials at several world-renowned medical institutions, is positioned for imminent FDA submission and subsequent market launch targeted.

11/21/2017—Announced the full integration of the CSS wireless device into its late stage, ongoing clinical trials being conducted at Thomas Jefferson University. The wireless system is the key component of the novel device’s efficient and user-friendly design.



11/15/2017—Announced a partnership with Rogan Molding Technologies. The Northbrook, IL company will be the exclusive manufacturer of the patient-interfacing gel pad for CVR Medical’s CSS. Founded in 1934, Rogan Molding Technologies is a staple organization in original equipment manufacturing and a global leader in the injection molding industry. Being ISO 9001 and 13485 certified, their cleanroom facilities are to meet the highly specialized needs of CVR Medical’s CSS device. Their experience and knowledge creating durable products with design flexibility and cost-efficiency has given CVR Medical great confidence in this piece of their novel device as it moves toward market launch.

09/28/2017—Announced the addition of Mr. Tim Knisley as Director of Finance and Controlling. Mr. Knisley has been hired to spearhead the building of CVR Medical’s financial systems as they transition from research and development-based to commercial-ready with the launch of the CSS device.

09/20/2017—Entered discussions with Key Opinion Leaders in the Chinese cardiovascular health industry, with whom the organization intends to extend membership on the executive board. The medical and business influence of these leaders are intended to fuel the growth of international opportunities for CVR Medical and its CSS device. In addition, CVR Medical announced the start of negotiations with several prominent Chinese distribution groups. This comes after a successful meeting with the leadership of the Chinese healthcare industry. The Company believes that this sets the trajectory of CVR Medical’s entry into the Chinese market in H2 2018, subsequently to follow its domestic launch.

09/14/2017—Announced the addition of Mr. Alan Langston to the Company’s executive staff. Mr. Langston assumes the position of Vice President of Sales and Marketing, responsible for creating and implementing market entry strategies for the Company’s CSS device.

09/08/2017—Announced that Jeremy Poirier has provided his resignation as a director of CVR Medical to pursue his other business interests. Mr. Poirier will remain on as a consultant with the Company. Going forward, CVR Medical wishes to maintain a board size of five directors and therefore will not seek to replace Mr. Poirier’s seat.

09/07/2017—Announced that advisory staff member Dr. Phillip J. Bendick, PhD, has released a summarized report on data from the tertiary clinical trials for the CSS device at Thomas Jefferson University. His report views initial evaluations as successful, and confirms the device’s value and efficiency. Dr. Bendick’s report reviews the most pertinent features of the data collected from these first trials. “From a clinical standpoint [...] the most important point is likely that the CSS, in a statistical sense, is very specific,” he states. Nearly all of the tested patients that had carotid artery stenosis were identified without an “overread,” an important measure which allows doctors to recommend steps for further care with confidence. “From a development standpoint [...] the greatest value of this latest data is the guidance it has provided in signal analysis.” Dr. Bendick notes that CVR Medical will derive substantial benefit from the device’s ability to separate and use only high quality sub-sonic sound during application. This ensures that background noise that could otherwise skew results will not be confused as signals for narrowing arteries with higher pressure. “Going forward, this ability [...] should improve even more the accuracy of the CSS to categorize a patient’s disease severity,” he concludes.

08/22/2017—Announced the addition of Dr. Phillip J. Bendick, PhD, to the Company’s advisory staff. Dr. Bendick, a renowned medical sonographer and researcher, will assist CVR Medical in the organization of expanded clinical trials for the CSS device. Dr. Bendick brings a wealth of knowledge and an extensive network to CVR Medical. Since 1971, he has worked, taught, and presented at medical institutions across the world, making seminal contributions to the field of vascular sonography.

08/08/2017—Announced that the Company has signed a letter of intent (LOI) with Canon Virginia, Inc. (CVI), Canon U.S.A., Inc.’s domestic manufacturing subsidiary, for the manufacturer of CVR Medical’s CSS. CVR Medical’s pairing with CVI, after years of development and growing anticipation for its ground-breaking medical technology, is a landmark achievement and a testament to its industry-changing potential. With this collaboration in place, CVR Medical is confident taking its product to market as it plans to leverage CVI’s existing industry relations to maximize production value as the device scales to meet its high demand potential.

06/29/2017—Announced that Thomas Jefferson University Hospital–Jefferson Clinical Research Institute has issued an initial trial report, summarizing the clinical trial progress of the CSS under the supervision of Principal Investigator Dr. David Whellan MD, MHS, FACC, FAHA. Dr. Whellan commented, “The ENTICES (Evaluation of a Novel Technique to Investigate CAS piezo-Electric Sensors) Study, assessing the CVR Medical’s CSS against current ultrasound technology, continues to enroll at a robust pace. The Jefferson Clinical Research Institute currently has data on over 125 within the study. A major factor in the successful enrollment has been the ease at which CSS data can be acquired, which allows participants to have test studies performed quickly. We look forward to completing enrollment and having results to share.”

06/02/2017—Announced that CVR Medical has obtained TSX Venture Exchange approval to issue 243,850 common shares of CVR Medical at a deemed price of \$0.3375 per share as payment to the Lubow Group that was due for their consulting services pursuant to a consulting agreement with an effective date of January 12, 2017. The Shares are subject to a four-month hold period expiring on September 30, 2017.

05/25/2017—Announced an update of its clinical trials of the CSS being conducted through the Jefferson Clinical Research Institute at Thomas Jefferson University under the supervision of Dr. David J. Whellan. Tertiary clinical trials have now been underway for four months at multiple site locations across the Thomas Jefferson University footprint. CVR Medical is pleased with current trials’ progress, and all milestones and timeline projections are essentially moving ahead as planned. Additional devices have and are being introduced in an effort to increase data acquisition, while concurrently attempting to shorten the timeline to FDA submission.

05/12/2017—Announced that it had entered into a consulting agreement with Lubow Group, a Florida Sole Proprietorship, with an effective date of January 12, 2017. Pursuant to the Consulting Agreement, after the initial 60-day term of the Consulting Agreement, CVR Medical has the option to pay Lubow the \$60,000 (C\$82,300) that was due for their consulting services by the issuance of common shares of CVR Medical. The parties have agreed to the payment for the consulting services by way of the issuance of an aggregate of 243,850 common shares of CVR Medical, at a deemed price of \$0.3375 per share to Lubow.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by CVR Medical Corp. (“CVR Medical” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in CVR Medical’s statements on its financial and other reports filed to the Canadian System for Electronic Document Analysis and Retrieval (SEDAR), as well as other forms filed from time to time.

The content of this report with respect to CVR Medical has been compiled primarily from information available to the public released by the Company through news releases, presentations, Annual Reports, and SEDAR filings. CVR Medical is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by CVR Medical or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, CRA has been compensated by the Company in cash of forty-four thousand dollars, fifty thousand shares, and a three-year option to purchase shares at the current share price for its services in creating this report and for updates.

Investors should carefully consider the risks and information about CVR Medical’s business, as presented in the Company’s Annual Information Form (AIF) filed to SEDAR. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed herein are not the only risks that the Company faces. Additional risks and uncertainties not presently known to CVR Medical or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, CVR Medical’s business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company’s shares could decline.

This report is published solely for informational purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. Additional information about CVR Medical and its public filings, as well as copies of this report, can be obtained in either a paper or electronic format by calling (403) 262-9888 or (734) 718-5115.

INDUSTRY CONDITIONS AND RISKS

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 CVR Medical’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 its products and future products. Failure of these new products to achieve significant market share could have material adverse effects on the CVR Medical’s long-term business, financial condition, and results of operations.

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

The successful commercialization of CVR Medical’s technology is crucial for its success. Even if the Company’s technology is shown to be less costly and more effective, CVR Medical 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, CVR Medical’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 U.S. clearance through the 510(k) process, a manufacturer must identify an existing “predicate” device from which to compare the new technology. Clearance in the U.S. is the most important clearance 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 and approval.

Inability to complete future research and development and engineering projects in a timely manner could have a material adverse effect of CVR Medical’s 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; and
- delays 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 CVR Medical keeps pace with changing technologies, it could lose existing customers and fail to gain new customers. In order to compete effectively in providing medical diagnostic solutions for healthcare providers, CVR Medical 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 CVR Medical is still developing and if the industry adopts test criteria that are different from internal test criteria of the Company, its competitive position would be negatively affected. The Company’s 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 Company’s patents.

If the Company is not able to adequately protect the intellectual property, then CVR Medical 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 the Company’s technologies and product candidates, as well as successfully defending third-party challenges to such technologies and candidates. CVR Medical will be able to protect its 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 the Company has 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 CVR Medical’s 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 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 CVR Medical’s patents. Accordingly, the

Company cannot predict with any certainty the range of claims that may be allowed or enforced concerning its patents.

CVR Medical may also rely on trade secrets to protect its 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 its consultants and scientific and other advisors, they may unintentionally or willfully disclose CVR Medical's 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 CVR Medical is not able to maintain patent or trade secret protection on its technologies and product candidates, then the Company may not be able to exclude competitors from developing or marketing competing products, and it 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 CVR Medical 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 CVR Medical 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 its position in the future. Other parties may own patent rights that the Company might infringe, and CVR Medical's competitors or other patent holders may assert that the Company's products and the methods that it employs are covered by their patents. These parties could bring claims against CVR Medical 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, CVR Medical 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 Company's patents may become obsolete and unmarketable if CVR Medical is unable to respond adequately to rapidly changing technology and customer demands.

The medical diagnostic industry is characterized by rapid changes in technology and customer demands. As a result, products and software of CVR Medical 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. CVR Medical 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, CVR Medical 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.

CVR Medical'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 CVR Medical'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 to 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 CVR Medical's anticipated high manufacturing standards, the Company cannot completely eliminate the risk of errors, defects, or failures. If CVR Medical 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 U.S. FDA Quality System Regulation compliance in the operation of their facilities, products, and manufacturing processes. Any adverse action by the FDA against the Company's suppliers or manufacturers could delay supply or manufacture of component products required to be integrated or sold with CVR Medical'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 CVR Medical's sales, contractual commitments, and financial forecasts may be significantly affected by any such delays

Glossary

Aneurysms—An excessive localized enlargement of an artery caused by a weakening of the artery wall.

Arteriovenous malformations (AVMs)—A congenital disorder of blood vessels in the brain, brainstem, or spinal cord that is characterized by a complex, tangled web of abnormal arteries and veins connected by one or more fistulas.

Asymptomatic—A condition or a person producing or showing no symptoms.

Atherosclerosis—A disease of the arterial blood vessels, in which the walls of the arteries become thickened and hardened by plaques. Plaques are composed of cholesterol and other lipids, inflammatory cells, and calcium deposits; also called “hardening of the arteries.”

Atrial fibrillation (AF)—An irregular, rapid heart rate that may cause symptoms like heart palpitations, fatigue, and shortness of breath. Also known as Afib.

Bifurcation—The division of something into two branches or parts.

Bruit—The abnormal sound generated by turbulent flow of blood in an artery due to either an area of partial obstruction; or a localized high rate of blood flow through an unobstructed artery. The bruit may be heard by pressing a stethoscope to the skin over the turbulent flow and listening. Most bruits occur only in systole, so the bruit is intermittent and its frequency dependent on the heart rate. Anything increasing the blood flow velocity such as fever, anemia, or hyperthyroidism, can increase the amplitude of the bruit.

Carotid artery (arterial)—Either of the two large arteries, one on each side of the head, that carry blood to the head and that divide into an external branch supplying the neck, face, and other external parts, and an internal branch supplying the brain, eye, and other internal parts.

Carotid Stenotic Scan (CSS)—A screening tool designed to detect and measure carotid arterial stenosis or occlusion for the purpose of identifying patients at risk for ischemic stroke.

Cerebral angiogram—A diagnostic test that uses an X-ray. The X-ray produces a cerebral angiogram that can help a doctor find blockages or other abnormalities in the blood vessels of a patient’s head and neck.

Cholesterol—A fat-like substance that is made by the human body and eaten in animal products. Cholesterol is used to form cell membranes and process hormones and vitamin D. High cholesterol levels contribute to the development of atherosclerosis.

Class II (FDA) product—One of the three FDA categories of medical devices, based on the level of risk. Class II devices are medical devices that pose a moderate level of risk to the user, and normally require a regulatory submission before they can be legally marketed. Examples of Class II devices are condoms, intravenous administration sets, sutures, and inflatable blood pressure cuffs.

Computed tomography angiography (CTA)—A computed tomography (CT) scan is a special X-ray tests that produce cross-sectional images of the body using X-rays and a computer technique. A CTA is a CT scan used to visualize arterial and venous vessels throughout the body. This ranges from arteries serving the brain to those bringing blood to the lungs, kidneys, arms and legs.

De Novo application—An FDA alternative risk-based pathway to classify novel medical devices that had automatically been placed in Class III after receiving a “not substantially equivalent” (NSE) determination in response to a premarket notification [510(k) submission]. Devices that provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicated device, can be classified into Class I or Class II through a *de novo* classification request and may be marketed and used as predicates for future premarket notification [510(k)].

Dirty blood—Blood that has passed through the capillaries of various tissues other than the lungs, is found in the veins, in the right chambers of the heart, and in pulmonary arteries, and is usually dark red as a result of a lower content of oxygen.

Duplex Doppler ultrasound (DUS)—A noninvasive test that can be used to estimate the blood flow through the blood vessels by bouncing high-frequency sound waves (ultrasound) off circulating red blood cells.

Embolic stroke—A type of ischemic stroke that occurs when a blood clot or a cholesterol plaque wanders into the brain and becomes trapped inside an artery.

FDA 510(k)—A premarket submission made to FDA to demonstrate that a medical device to be marketed is at least as safe and effective to a legally marketed device, and thus not subject to *premarket approval (PMA)*. Although laboratory testing is almost always a requirement, human data requirements are left to the discretion of the FDA. The FDA does not “approve” 510(k) submissions. It “clears” them. It is not legal to advertise a 510(k) cleared device as “FDA-approved.”

Hemorrhagic stroke—Stroke caused by the rupture of a blood vessel in the brain.

Intersocietal Accreditation Commission (IAC)—An organization that accredits imaging facilities and hospitals specific to echocardiography. IAC accreditation is a means by which facilities can evaluate and demonstrate the level of patient care they provide.

Ischemic stroke—A stroke caused by an interruption or blockage of oxygen-rich blood flow to an area of the brain; caused by a blood clot, atherosclerosis, vasospasm, or reduced blood pressure.

LDL (bad) cholesterol—Low-density lipoprotein cholesterol is the primary cholesterol molecule. High levels of LDL, nicknamed “bad” cholesterol, increase the risk of atherosclerosis.

Magnetic resonance angiography (MRA)—A magnetic resonance imaging (MRI) exam is a test that uses powerful magnets, radio waves, and a computer to make detailed pictures inside the body. An MRA is a type of MRI of the blood vessels. Unlike traditional angiography that involves placing a tube (catheter) into the body, MRA is noninvasive.

Occlusion—An obstruction or closure of a passageway or vessel.

Patent Cooperation Treaty (PCT)—An international patent law treaty that provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. As of 16 March 2017, there were 152 contracting states, including the majority of the industrialized countries.

Pre-market approval (PMA)—The FDA's process of scientific and regulatory review to evaluate the safety and effectiveness of new medical devices. A successful PMA submission results in approval of the new device. PMA standard is higher than is required for 510(k) submissions, as human use data from a formal clinical study is almost always required. PMA devices can be legally advertised as “PMA-approved” or “FDA-approved.”

Sonography—Using the reflections of high-frequency sound waves to construct an image of a body organ (a sonogram).

Stenosis—The abnormal narrowing of a passage in the body, such as an artery or vein.

Stroke—The sudden death of brain cells due to lack of oxygen, caused by blockage of blood flow or rupture of an artery to the brain. Stroke symptoms normally include sudden loss of speech, weakness, or paralysis of one side of the body.

Symptomatic—Exhibiting or involving symptoms.

Systole—The phase of the heartbeat when the heart muscle contracts and pumps blood from the chambers into the arteries.

Thrombosis—Local coagulation or clotting of the blood in a part of the circulatory system.

Transient ischemic attack (TIA)—A “mini” stroke caused when blood flow to the brain is temporarily interrupted and then restored; causes no permanent brain damage.

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CRYSTAL

RESEARCH ASSOCIATES

— FACTS WITHOUT FICTION —

About Our Firm: For the past decade, Crystal Research Associates, LLC has successfully articulated the exceptional stories of small- and mid-cap companies to the Wall Street investor community. Our methods are well-established and diverse, from compiling and disseminating objective, factual information for both institutional and retail investor audiences to capitalizing on our expansive line of targeted distribution channels, which include industry-leading financial data and information providers. Our distribution efforts are accompanied by the use of prominent social media channels and by strategic and targeted appearances on national news programs and print media.

Crystal Research Associates is led by Wall Street veterans, Jeffrey Kraws and Karen Goldfarb. Together, Kraws and Goldfarb have built a unique business model, capitalizing on decades of experience as an award-winning sell-side analyst team to produce institutional-quality industry and market research in a manner that is easily understood by investors and consumers. Our firm's approach has been proven successful over the years as our products are published and available on Bloomberg, Thomson Reuters, S&P Capital IQ, FactSet, and scores of other popular forums.