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*CardioComm Solutions, Inc.*

*EKG-TSX.V*

## EXECUTIVE INFORMATIONAL OVERVIEW®

August 6, 2013



### **CardioComm Solutions Inc.**

**CardioComm Solutions, Inc.**

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Ticker (Exchange)	EKG (TSX.V)
Recent Price (08/06/2013)	C\$0.12
Shares Outstanding	~100.1 million
52-week Range	C\$0.09 - C\$0.43
Market Capitalization	~C\$12 million
Average 3-month Volume	51,595
Insider Ownership >+5%	60.66%
EPS (Qtr. ended 03/31/2013)	(C\$0.00)
Employees	19



#### **CardioComm Solutions' HeartCheck™ PEN Device**

The first FDA-cleared, handheld, over-the-counter (OTC) ECG monitor for patient diagnosis and management.



### **Company Description**

CardioComm Solutions, Inc. specializes in software engineering of information management systems and integration of bio-monitoring devices for the cardiac and **telemedicine†** markets. The Company's integrated **electrocardiogram (ECG)** and **arrhythmia** monitoring products and services enable patients, medical professionals, and healthcare experts to quickly and easily manage patient information and ECG recordings in a secure, reliable environment from anywhere in the world—specifically to record, view, analyze, and store patients' ECGs for diagnosis and treatment of cardiac disorders. Rated as the best enabling technology for cardiac rhythm monitoring in 2012 by Frost & Sullivan, CardioComm Solutions' technology is used in a number of products dedicated to improving the quality of life for anyone who has been diagnosed with, or who may be at risk for, cardiovascular disease. The Company recently introduced a new handheld ECG recording device, the HeartCheck™ PEN ECG, which represents the first in-home, consumer-targeted health monitoring technology for OTC markets in the past 30 years. The HeartCheck™ devices (which also include a prescription HeartCheck™ Handheld ECG Monitor) are supported by software programs and patent-pending "SMART Monitoring services," which the Company has developed to enable 24/7 patient monitoring and objective medical interpretation, with the capacity for integrating ECG reporting into existing **electronic medical records (EMRs)**, among other innovative features.

### **Key Points**

- Over the past two years, CardioComm Solutions has worked to obtain regulatory clearances for its products in the U.S., Canada, and Europe, and has been establishing a global distribution network. The Company has clients in roughly 20 countries with its GEMS™ and GlobalCardio™-branded software products and is working to ramp-up sales of its HeartCheck™-branded ECG devices.
- To the Company's knowledge, it is the first provider of a complete, full cycle of market-tested ECG monitoring services, which includes the HeartCheck™ PEN. Worldwide sales of ECG telemetry devices could reach \$1.25 billion by 2017, driven by an aging global population, increasing incidence of cardiovascular diseases, and technological innovations expected to boost adoption.
- The ECG management systems market is expected to expand over the next several years as hospitals strive to increase efficiency, reduce costs, and improve patient care by connecting ECG devices to a centralized database. CardioComm Solutions has already licensed its software to several major enterprises, including Philips Healthcare, GE Healthcare, Kaiser Permanente, and the Mayo Clinic.
- In 2014, the Company plans to release software upgrades for increased compatibilities as it looks to enable monitoring of multiple biometrics, such as blood pressure and blood glucose readings, as well as heart ECG readings, within one integrated software solution.
- In January 2013, CardioComm Solutions received a \$1 million line of credit from MD Primer, which it may use as needed. As of the first quarter 2013, the Company's cash position was ~\$54,000.

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## Executive Overview

CardioComm Solutions, Inc. (“CardioComm Solutions” or “the Company”) develops and markets software for informational management solutions used within the diagnostic cardiac and telemedicine markets. The Company’s proprietary electrocardiogram (ECG) telemetry and ECG viewer technology is classified as a **Class II medical device** on its own in North America and is used to reliably record, view, analyze, and store patients’ ECGs in an innovative and useful manner. This technology allows physicians to review and diagnose patients’ heart readings over a virtual healthcare network in real time and with potentially life-saving speed, reducing the time between onset of symptoms and treatment. Patients who are suspected of having or who are known to have cardiac arrhythmias, including high-risk patients with **atrial fibrillation (AF)**, may benefit from this technology, which is capable of sending immediate alerts as patients’ cardiac events are detected. This technology may even detect cardiac events before the patient is aware of symptoms.

The Company’s integrated product line, as summarized in Figure 1, primarily includes the areas listed below.

- Software marketed under the brands GEMS™ (Global ECG Management Systems), GEMS™ Home, and GlobalCardio™
- Hardware marketed under the HeartCheck™ brand, including HeartCheck™ Handheld ECG Monitors, used in a medical setting; and CardioComm Solutions’ most recently introduced device, the HeartCheck™ PEN ECG, the first U.S. Food and Drug Administration (FDA)-cleared, handheld, over-the-counter (OTC), consumer-targeted ECG product capable of recording and displaying ECG data without a physician’s prescription.
  - As well, the patent-pending SMART Monitoring service establishes the equivalent of a patient/physician relationship. These medical call center services, branded HeartCheck™ SMART Monitoring services, enable consumers to have their heart rhythms recorded and the resultant ECGs analyzed and interpreted by a physician, ECG coordinating technician, or both, who can read and diagnose a patient’s ECG within 30 minutes, 24 hours a day, 7 days a week, 365 days a year.
- Third-party ECG monitoring hardware for which drivers have been specifically developed to enable these devices to work with the Company’s software

Figure 1

### PRODUCTS AND SERVICES SUMMARY

#### GEMS™ Home Desktop Application



#### HeartCheck™ PEN device available to consumers



#### HeartCheck™ ECG device available with a prescription



#### HeartCheck™ SMART Monitoring available with HeartCheck Handheld Devices



Source: CardioComm Solutions, Inc.

Importantly, CardioComm Solutions has earned the **ISO 13485 certification**, is **Health Protection Branch (Canada)** approved, is compliant with the **Health Insurance Portability and Accountability Act of 1996 (HIPAA)**, and has received FDA market clearance for its software devices.

## **Cardiovascular Disease**

Cardiovascular disease is a highly prevalent medical condition and is the leading cause of death in the U.S. and worldwide for both men and women. A person's greatest chances of surviving and avoiding long-term heart damage resulting from a cardiovascular event occurs when emergency treatment is administered early on, notwithstanding that roughly 50% of deaths from a heart attack happen *before* a patient has a chance to seek help. Similarly, strokes, on average, kill one person in the U.S. every four minutes, and in cases where the patient survives a stroke, there is still likely to be a subsequent long-term disability.

CardioComm Solutions' products are targeted toward helping improve outcomes for people who are prone to, or who are suffering from, cardiovascular disease. The Company's ECG proprietary software solutions enable telemetry devices to be used in the remote monitoring of patients for diagnosis of cardiac arrhythmias, such as AF. Those people for whom ECG monitoring is most relevant are those who are at risk for any of the following conditions: heart attacks, **cardiomyopathy**, high blood pressure, congenital heart defects, heart valve disease, coronary heart disease, sleep apnea, and heart failure, among other afflictions. By having access to accurate, immediate cardiac data recorded through patient monitoring technologies, such as those available from CardioComm Solutions, the likelihood of preventing or surviving a severe cardiac event greatly increases.

## **Products and Services**

### *Software*

CardioComm Solutions has been a provider of ECG management software solutions for 17 years. Using proprietary technologies and an industry leading ECG (signal) viewer, and by offering flexible open-ended work flow solutions, the Company provides technology that is compatible with the majority of the world's cardiac event monitors, including those ECG recording devices intended for the home as well as for medical setting **telehealth** markets. The Company's software products for the diagnosis of cardiac abnormalities, marketed as GEMS™ and GlobalCardio™ (described in brief below and in greater detail on pages 25-26), have been used worldwide since 1999, the date of the GEMS™ FDA clearance. The Company's software is typically sold into hospitals, call centers, and physician's offices for use with patients under prescription. CardioComm Solutions' software products have also been sold through a combination of an external distribution network and CardioComm Solutions' North American-based sales team.

### GEMS™ (Global ECG Management System) and GEMS™ Home

CardioComm Solutions' software for cardiac event monitoring, called GEMS™ (Global ECG Management System), can transmit, receive, manage, and store patient information and ECG files from anywhere in the world through computers, wireless devices, enterprise networks, telephones, and/or the Internet. As a Class II medical device in North America and a **Class I medical device** in the European Union, the GEMS™ group of software solutions offers a credible and true management tool designed to provide for the needs of busy clinics and healthcare professionals, and can be likened to an electronic medical record (EMR) or a personal health record, enabling physicians to login, track, notate, and record patients' diagnoses. As well, it is a cost-effective alternative to current hardware receiving systems, since it can be installed on most desktop computers for use in tracking and storing comprehensive patient information. The Company also markets the GEMS™ Home edition, which is a heart rhythm management solution for consumers (versus the professional GEMS™ platform). GEMS™ Home, which is based on the GEMS™ software, functions as a desktop application bundled with the software for CardioComm Solutions' HeartCheck™ PEN.

The other component to GEMS™, called GUAVA, is CardioComm Solutions' ECG viewer software. Significantly, with the Company's regulatory-approvals, the ECG viewer enables ECGs to be interpreted over local area networks (LANs) or the web—a characteristic not offered by most ECG management systems. GUAVA is nested inside GEMS™, which takes the signal from ECG recording devices and digitally displays it on a computer screen grid in a manner similar to a traditional paper-based ECG. The advantage of CardioComm Solutions' "grid" is that it is digital, allowing filtering and magnification of recorded ECGs to look for particular sections of the waveform with higher fidelity. As well, it has electronic **calipers** that automatically calculate durations of different waves or waveform morphology to permit comparisons of differences in durations.

#### Developing a Mobile Cardiac Telemetry (MCT) Module

With the Company's GEMS™ and GlobalCardio™ software cleared as a **Class I and II medical products** globally, this continues to drive the support and interest from different device manufacturers requiring software to operate their devices. One such instance is CardioComm Solutions' development efforts on a Mobile Cardiac Telemetry (MCT) module for its GEMS™ software, with a goal of completing this product by year-end 2013. There is an original equipment manufacturer (OEM) of an MCT device, called TZ Medical, Inc., which is focused on the **electrophysiology (EP)**, cardiac, and critical-care markets. In February 2012, CardioComm Solutions and TZ Medical entered into a device integration and distribution agreement for the MCT ECG and arrhythmia management market. The TZ Medical device is intended to have the capacity to work on other cellular networks, with a goal of enabling MCT billing by smaller independent call centers in the U.S. CardioComm Solutions expects this agreement could provide the Company with a large base for licensing its MCT technology and enable wireless monitoring from a global platform. The MCT efforts are being built upon the Company's wireless event software (GEMS™ Air), which has, since 2009, supported GSM-enabled ECG transmissions manufactured by Vitaphone GmbH and Braemar, a subsidiary of CardioNet (to be named BioTelemetry in July 2013), and the world's largest developer and producer of patient-worn diagnostic electrocardiology devices.

#### Software Product Licensing Relationships

CardioComm Solutions is working to become a preferred software provider of cardiac ECG management systems. Globally, companies are rapidly developing new cardiac monitoring technologies both for the consumer market as well as for prescribed in-hospital or physician-based use. A selection of some of these technologies is provided in the Competition section on pages 39-44. Since software development is a costly and complex undertaking, many companies would rather outsource these efforts.

CardioComm Solutions currently has a multi-year license with Philips Healthcare, part of Koninklijke Philips Electronics NV (PHG-NYSE), which uses CardioComm Solutions' ECG viewer. In addition, GE Healthcare (a division of General Electric [GE-NYSE]), sells a private-label version of CardioComm Solutions' GEMS™ software (as described in the below paragraph). The Company further has software licenses for GEMS™ with organizations including Kaiser Permanente, the Mayo Clinic, and the Sick Children's Hospital in Ontario. Moreover, CardioComm Solutions has announced that it is in discussions with Polar Electro Oy and Avery Dennison Medical, part of Avery Dennison Corp. (AVY-NYSE) (under the new name Vancive for medical products: <http://vancive.averydennison.com>).

CardioComm Solutions re-announced the private labeling agreement with GE Healthcare's Diagnostic Cardiology business in January 2013. The agreement is complementary to an existing OEM agreement between the two companies and permits GE Healthcare's MARS Event Station and MARS Event Station Lite software, provided by CardioComm Solutions, to be filed with the Therapeutic Products Directorate of Canada. The authorization will also permit GE Healthcare and Health Canada to cross-reference the Company's original GEMS™ medical device license materials, licensed by Health Canada under License No. 36225, in support of the GE Healthcare application. This authorization is valid until June 30, 2014.



## Potential Product Extensions

CardioComm Solutions is in the process of making software upgrades to its GEMS™ and ECG viewers. The Company reports that this project is on track to be completed by year-end 2013. The Company is also seeking to expand its software to become a multiple bioscience/biometric monitoring device, perhaps able to monitor up to 10 channels (e.g., pulse oximetry, blood pressure, and blood glucose) for use in either OTC or prescriptive fashion. The goal is for CardioComm Solutions' GEMS™ software to accommodate all monitoring, where it will only be necessary to operate one program instead of multiple programs. Ultimately, CardioComm Solutions seeks to modify the viewer to perform multiple biosigns without the need for additional FDA clearances on GEMS™ and GlobalCardio™.

## *Hardware*

### HeartCheck™ Brand: Handheld and PEN ECG Device

CardioComm Solutions markets the HeartCheck™ brand of products, which includes the HeartCheck™ Handheld ECG Monitor and the HeartCheck™ PEN ECG device—both of which are portable, easy to operate devices that can take accurate heart readings in only 30 seconds. The HeartCheck™ PEN, which is CardioComm Solutions' newest device, was FDA cleared for consumer use in December 2011 as the world's first FDA-cleared, handheld ECG recording device that can be unlocked under the direction of a physician to allow patients to take their own ECGs the moment a symptom is felt—at home, at the gym, in the office, etc. This is important as it brings ECG monitoring into the hands of consumers. The clearance also included GEMS™ Home, a consumer heart rhythm management solution based on CardioComm Solutions' proprietary software, which can be converted into an ECG viewing and personal ECG record management solution.

The HeartCheck™ PEN ECG device works with CardioComm Solutions' GEMS™ Home software and is part of the Company's HeartCheck™ patent pending SMART Monitoring service (as described below). The device, which retails for \$259 globally, captures an individual's heart reading using an ECG recording as the individual holds the device in their hand. The HeartCheck™ PEN can then be connected to a computer via a USB cable (included) to view the heart rhythm reading, which will report heart rate, and then enable the consumer to request a reading be performed by a physician, clinic, or ECG Coordinating Center for an ECG analysis. The SMART Monitoring results may be printed or emailed by the consumer and taken with them when they visit a physician or cardiologist prior to a scheduled appointment or when they decide to visit an emergency department or walk-in clinic.

In 2012, CardioComm Solutions achieved five different medical device clearances for its HeartCheck™ PEN, including two U.S. FDA clearances, the first of which was for the use of the Heart Check™ PEN as a prescription product and the second for the use of the HeartCheck™ PEN as an OTC product (cleared by the FDA in only five days). In addition to its FDA clearances in 2012, CardioComm Solutions also received two similar clearances from Health Canada in September 2012 and, in November 2012, received a CE Mark which confirms the product's compliance with EU legislation and enables the free movement of products within the European market. CardioComm Solutions is now positioned to be able to sell the HeartCheck™ brand of products globally. Additional clearances in regions such as the Middle East, Asia, and Africa are being undertaken in association with preferred local distributors in these areas.

## *Services*

### HeartCheck™ SMART Monitoring

The patent-pending HeartCheck™ SMART Monitoring service enables individuals to manage the transfer of their recorded ECGs to a pre-designated ECG reading service in North America. On the first use, the ECG signal is not displayed, permitting the consumer to have a heart rhythm reading that will designate whether the recorded rhythm is normal or unexpected, with the measured heart rate displayed. Once the first heart rhythm recording is sent for an ECG interpretation, the consumer will receive an interpreted ECG report through the free GEMS™ Home software, a report that is similar to what is provided following diagnostic ECG reading from hospitals. CardioComm Solutions' patent-pending SMART Monitoring service technologies enable consumers to have their heart rhythms analyzed and interpreted, and then to unlock the HeartCheck™ PEN and GEMS™ Home to display ECGs during recording. After being recorded, the ECGs can be seen on the device or computer for viewing and then

printed for review after the recordings are transferred to GEMS™ Home. The Company's patent-pending SMART Monitoring technologies are intended to enable any approved HeartCheck™-branded personal health monitoring device that is capable of displaying biosign wave forms and/or images to be used for remote access interpretation. A biosign medical call center employs technicians and physicians who can interpret diagnostic images, as is currently used for the HeartCheck™ ECG readings, within 30 minutes, 24 hours a day, 7 days per week, 365 days a year. Once results are transmitted back to the GEMS™ Home belonging to the consumer, the ECG reports may be printed for review and shared with physicians during scheduled visits or used when a visit to an emergency room or walk-in clinic is needed.

#### Partnership with SPI Scanning LLC

In April 2013, CardioComm Solutions announced that it had formed a partnership with Texas-based SPI Scanning LLC (SPI), a national healthcare testing corporation established under U.S. federal guidelines as an independent diagnostic testing facility (IDTF) and a provider of Holter and event scanning services to hospitals and doctor's offices around the world. SPI is providing CardioComm Solutions' patients with around-the-clock access to rapid physician ECG interpretations. SPI specializes in overflow scanning to assist busy centers with rapid ECG processing by certified professionals. Through this relationship, CardioComm Solutions is able to ensure a 30-minute ECG interpretation service in support of its HeartCheck™ PEN and SMART Monitoring service. The call center model may be expanded to include more medical call centers in Canada, the U.S., or globally in response to distribution requirements, access to personal health information regulations, or simplified work flow solutions, especially when ECG and multiple biosign reading volumes increase.

#### Partnership with SunGard

On September 5, 2012, the Company announced a three-year relationship with SunGard Data Systems Inc., (SunGard) to support Enterprise Cloud Services (ECS) and provide co-location facility resources for the housing of CardioComm Solutions' SMART Monitoring services. The multi-year agreement was an integral step of the Company's 2012 sales and marketing plan since the ECS is scalable and can support any demands put on the SMART Monitoring service not just in support of North American HeartCheck™ PEN clients but also to match any global demand that may result from the international HeartCheck™ distributor networks being developed. Using SunGard as CardioComm Solutions' resources provider means the Company's customers will have access to the SMART Monitoring service immediately.

SunGard is an international organization operating in more than 70 countries. By leveraging the Company's virtual software solution capabilities with SunGard's multi-country facilities network, CardioComm Solutions believes that it can reduce the cycle time to ramp up and execute an aggressive, cost-effective go-to-market strategy within other countries while also meeting requirements for privacy compliance, ISO standards, and protections of FDA, Health Canada, and CE mark clearances. Such clearances and credentials are intended to help differentiate CardioComm Solutions as it seeks to become a global medical and consumer telemedicine solutions provider.

### **Marketing and Distribution**

CardioComm Solutions' products are currently sold worldwide to hospitals, call centers, and physicians' offices through a combination of an external distribution network and the Company's North American-based sales team. The Company is also undergoing a specific strategy to ramp-up sales of its HeartCheck™ devices, intending to promote its HeartCheck™ PEN (combined with its SMART Monitoring service) to those at risk for developing arrhythmia-based cardiac disease due to underlying conditions, especially due to hypertension and diabetes as well as those taking high-risk medications.

In addition, the Company intends to target consumers over the age of 40 who are interested in the preservation of their health. Other populations likely to benefit from CardioComm Solutions' arrhythmia monitoring and traditional 12 lead ECG products include public health screening organizations, insurance companies, early discharge or high-risk cardiovascular patients post-surgery, athletes, seniors, nursing home residents, home care facilities, visiting in-home care givers, correctional facilities, and people in remote areas such as mines and cruise ships, among many others.

Since January 2013, CardioComm Solutions has received roughly a half dozen requests from companies that are in the traditional medical device arena—with their own sales forces who target physicians’ offices, hospitals, and clinics. Internationally, the Company has Non-Disclosure Agreements (NDAs) with a growing list of global distributors and device manufacturers in countries such as, but not limited to, Australia, Africa, Costa Rica, Greenland, India, Indonesia, Israel, Japan, Malaysia, Thailand, Turkey, the United Arab Emirates (UAE), and Vietnam.

Based on this interest, the Company has stated that it believes it could sign at least two agreements with device companies and at least three with country distributors going forward, which are expected to help sell CardioComm Solutions’ HeartCheck™ devices and/or the Company’s patent-pending SMART Monitoring service technologies into medical call centers, physicians’ offices, and hospitals. As well, distribution agreements are either in place, or are in progress, with North American-based distributors, pharmaceutical companies, pharmacy chains, heart associations, and portals for direct-to-consumer (DTC) advertising seeking to sell the HeartCheck™ PEN. These relationships are described in greater detail on pages 33-35.

### **iMedical Inc.**

In anticipation of a marketing initiative to target U.S.-based device development of new ECG monitoring products, CardioComm Solutions incorporated a U.S.-based subsidiary roughly two years ago called iMedical. In March 2013, CardioComm Solutions announced a pre-placement financing and joint venture deal ahead of an initial public offering (IPO) of iMedical. The joint venture entails an agreement with Toronto-based Sensor Mobility, a company that has developed cost-effective, autonomous sensing devices used to collect individuals’ vital statistics and to transmit that data via a proprietary and cost-effective cellular platform that will enable its bio-monitoring devices to work from anywhere in the world. CardioComm Solutions views the capacity for global cellular compatibility of a wearable medical monitoring device to be an unmet need in the global wireless monitoring market. Through this venture, iMedical is expected to develop core intellectual property assets combining those device technologies of Sensor Mobility and the software technologies of CardioComm Solutions into a wearable, ECG monitoring device equipped with **Global System for Mobile (GSM)** communications.

Specifically, such products could use CardioComm Solutions’ ECG management and remote access and interpretation software technologies as the core management platform for communication with the worn ECG recording devices. They are also anticipated to provide an interpretation environment for the review and diagnosis of ECGs received from monitored individuals from any global location and by medical healthcare professionals located anywhere in the world.

CardioComm Solutions expects iMedical to develop into an independently operated and financially independent organization and is to hold a 35% interest in iMedical. Under a brokered deal, equity shares in iMedical will likely be issued to high-net-worth individuals in exchange for \$4 million to fund development of this wearable, GSM-enabled, ECG monitor prototype. The senior management team of iMedical will hold one seat for the CEO of CardioComm Solutions, or a designate, and will hire its own CEO or senior director to oversee the iMedical business plan execution and development of its market. In addition to software and regulatory contributions, CardioComm Solutions will provide market development direction and will leverage its now global network of interested ECG technology solutions resellers and partners for the marketing and sale of iMedical’s wearable, GSM-enabled ECG sensor device.

### **Awards**

#### *Frost and Sullivan Award*

In a significant corporate milestone, CardioComm Solutions was recognized with the 2012 North American Frost & Sullivan Award for Enabling Technology, specifically for leveraging its SMART Monitoring service technology to launch a fully scalable and cost-effective ECG and arrhythmia monitoring solution. Each year, Frost & Sullivan presents this award to a company that has developed a technology that can benefit or revolutionize the industry. The award recipient has to have developed a system or enabling component of a system that eliminates a substantial hurdle in the development of technology.



## **Headquarters and Employees**

In 1989, the Company commenced operations under the name Harley Street Software Ltd., attempting to build a device and software company. In 1998, under a strategic realignment, the name was changed to CardioComm Solutions Inc. In 2007, following a 5-to-1 reverse stock split and due to a requirement by the TSX Venture Exchange (TSX.V), the name was changed to CardioComm Solutions, Inc. (adding a comma). CardioComm Solutions moved its headquarters to Toronto, Canada, in 2011 and maintains its R&D facilities, customer support, and software fulfillment from within its offices in Victoria, British Columbia, Canada. The Company currently employs 19 individuals and ramps up staffing through the use of short- and long-term contract positions as needed. The Company's stock trades on the TSX.V under the symbol "EKG" and, since the Company's FDA clearance announcement in January 2012, has traded every day the market has been open.

## Growth Strategy

In March 2012, CardioComm Solutions completed a private placement to raise up to \$1.7 million as the Company sought to quickly build up its infrastructure following the rapid FDA 510(k) clearance of its HeartCheck™ PEN ECG device and GEMS™ Home. The Company had anticipated a 10-month approval cycle, during which time it had planned to undertake a series of capital raises sufficient to support sales and marketing efforts as well as to propel establishment of production lines to support projected sales targets in the ensuing 2013 calendar year.

CardioComm Solutions secured their FDA clearance within five calendar days of the completed application submission date. As a consequence, the Company required a rapid cycle for capitalization proximal in time to the market's interest. The funds from the targeted \$1.7 million raise were earmarked for completing key programming projects and transitioning the HeartCheck™ PEN into production, including labeling, distribution, marketing, and all related infrastructure for the PEN, which are costly processes, especially when completed in a short cycle time. Where the Company had expected an October 2012 FDA clearance, CardioComm Solutions instead has now focused its efforts to be production-ready for North American sales in October 2013.

In addition to its efforts related to ramping up its HeartCheck™ PEN production and global sales opportunities, the Company is also in the process of signing additional collaborative agreements related to expanding use of its GEMS™ and GlobalCardio™ software licenses; expanding the use and sale of its HeartCheck™ devices as point-of-care ECG monitors; and focusing on commercializing its arrhythmia screening tools. Thus, with many important milestones achieved during 2012, 2013 is also expected to be an important year for the Company, with core growth in areas outlined below.

### Revenue Streams

The Company has multiple revenue streams available to it, as depicted in Figure 2 (page 11) and outlined below.

- *User Fees* incurred as individuals upload ECGs
- *Hardware Sales* from the Company's HeartCheck™ devices
- *Software Licensing Agreements* with established clients, such as Philips and GE Medical
- *New Software* that is expected to be developed and released in the near term
- *Third-Party Hardware Sales* stemming from the device-agnostic nature of CardioComm Solutions' software, where the Company has the capacity to sell other established ECG hardware recording devices with its software. Some of the existing device manufacturing clients include Burdick, CorScience, LifeWatch, MedNet, NorthEast Monitoring, QRS Diagnostics, Pulse Biomedical Systems, and Vitaphone. Additional device manufacturers of single and multi-lead ECG monitoring devices continue to contact the Company for the opportunity for integration with the CardioComm Solutions software and remote monitoring technologies. These include devices paired via Bluetooth to smartphones and home communication hubs, GSM transmission to centralized servers, and digital uploading over the Internet from device-docking stations. Opportunities exist for adding new devices that would service medical and OTC-consumer ECG monitoring markets. Given CardioComm Solutions' unique OTC 510(k) clearance and American and Canadian patent-pending coverage of SMART Monitoring-based service technologies for transforming OTC consumer products into devices capable of transmitting biosigns (previously restricted to prescribed medical devices), the Company believes that it is well positioned to capture a solid share of the market for home bio-monitoring services in North America and overseas.

Figure 2  
GROWTH STRATEGY

<b>User Fees:</b>	Data management, triage, and interpretation of ECGs transmitted to GlobalCardio™ call center software
<b>HeartCheck™ PEN and Handheld ECG:</b>	Sales and revenue from PEN and other HeartCheck™ branded devices
<b>Licensing Fees:</b>	Industrial equipment and service providers, such as Philips and GE Medical
<b>Third-Party Equipment:</b>	Sale of equipment integrated with CardioComm Solutions' back end solutions – MedNet, Burdick, NorthEast, Cardiac Science, and CoreScience
<b>Telemedicine Applications:</b>	Multi-device integrated solutions for consumers

*Source: CardioComm Solutions, Inc.*

### **Funding**

CardioComm Solutions is currently seeking additional funding in order to achieve the growth objectives listed below.

- Bring its HeartCheck™ PEN into mass production
- Address the associated costs of developing a sales and marketing plan in support of HeartCheck™ PEN sales and the SMART Monitoring service, which is a global initiative. This is intended to leverage the work that has already been started, where CardioComm Solutions has received interest from a multitude of distribution organizations globally (as described in greater detail on pages 33-35)
- Develop new platforms and releases of its software platforms—GEMS™ and GlobalCardio™—with the expectation of becoming capable of monitoring multiple diseases and enabled for multiple operating systems, where it could support Windows® and iOS operating systems, and develop applications to support smart-phones from Apple and Android manufacturers, as well as addressing the multi-language requirements of some of the Company's customers.

Because CardioComm Solutions has been able to expeditiously receive regulatory clearances, and due to its solid position as a software engineering organization capable of developing biosign monitoring applications to suit a variety of work-flow requirements, the Company may consider another private placement in the future should it believe it to be warranted in order to rapidly scale-up operations and develop a capital base that has not been available to the Company in recent years.

### **Strategic Partnerships**

CardioComm Solutions is pursuing a strategy of collaborating with companies, rather than competing with them, in building its products and solutions. Accordingly, the Company is in discussions with several foreign companies that have affordable hardware technologies and cellular network infrastructures but are believed to lack the expertise to activate these technologies with the appropriate software solutions. CardioComm Solutions seeks to sign additional collaborative agreements that relate to the following: (1) expanding its GEMS™ and GlobalCardio™ software licenses; (2) promoting greater use and sale of the HeartCheck™ devices as point-of-care ECG monitors; and (3) commercializing its community and at-risk population arrhythmia screening tools. To date, these strategies appear to be successful for the Company as end users in South America, Europe, Middle East, and Asia have expressed interest. As well, CardioComm Solutions has received interest from representatives in more than 50 countries regarding distribution rights for its products—signifying the potential prospects for expanding its markets.

### *iMedical*

In March 2013, CardioComm Solutions announced a pre-placement financing and joint venture deal ahead of an IPO of its U.S.-based subsidiary, iMedical. This subsidiary was incorporated approximately two years ago in anticipation of a marketing initiative to target U.S.-based device development of new ECG monitoring products. The Company has entered into an agreement with Canada's Sensor Mobility in order to develop and enable wearable ECG monitoring devices with GSM transmitting technology, where CardioComm Solutions' software fulfills device management and data interpretation roles. CardioComm Solutions is expected to hold a 35% interest in iMedical. Initial investors have been identified, and it is expected that all seed funding could be received within 2013.

According to CardioComm Solutions' March 11, 2013, press release, while no work will start until the first \$1 million is raised, both CardioComm Solutions and Sensor Mobility are preparing for a summer deployment of dedicated resources for initiation of their respective tasks. Once a 510(k) regulatory application for device clearance has been made to the FDA, the Company will likely begin fundraising for an iMedical IPO with the aim of raising at least five years of working capital. The iMedical company is expected to hire its own CEO.

With its involvement in iMedical, CardioComm Solutions is expected to recognize revenue from multiple opportunities, and will have a right of first refusal for bidding on all third-party-based software engineering contract work as it relates to ECG acquisition, management, and interpretation. CardioComm Solutions also expects to collect royalties from the licensing of its core GEMS™/GlobalCardio™/GUAVA™ software intellectual property and is to receive funds from any profit-sharing or payment of dividends as a shareholder. Of the \$4 million intended to be raised, approximately \$1.9 million is to be earmarked for Sensor Mobility and \$1.3 million to CardioComm Solutions for services to be provided to iMedical.

## Milestones

### Recent Milestones

CardioComm Solutions has achieved its stated objectives by recently accomplishing the following milestones.

- Attained five different device clearances for its HeartCheck™ PEN, including two FDA clearances in the U.S. for both prescription and OTC use, Health Canada approval (as well as Health Canada approval for the HeartCheck™ Handheld ECG), and a CE Mark extension to sell the HeartCheck™ ECG Monitor in Europe.
- Brought to market the HeartCheck™ PEN as the first handheld consumer OTC ECG product with associated software and the first new home bio-monitoring technology in 30 years.
- Achieved a five-day review period and approval process for the HeartCheck™ PEN as an OTC device (reducing the Company's production planning by roughly 10 months).
- Confirmed that it has filed for U.S. and Canadian patents for use of the Company's proprietary technologies in the automated, software-enabled and server-based unlocking of OTC, consumer-based, bio-monitoring devices. Under the U.S. and Canadian patents, filed on May 6, 2013, and May 8, 2013, respectively, the Company would be permitted to apply the statement "Patent-Pending SMART Monitoring Service Technologies" in its corporate materials until the application process has been completed. These patent applications, and the ability to state "Patent-Pending" in the Company's literature, are expected to permit CardioComm Solutions a less-encumbered expansion into North American markets.
- Contracted by the Heart and Stroke Foundation as the preferred provider to run an ECG screening program in Canada for the detection of cardiac arrhythmias with specific emphasis on the most difficult to find arrhythmia—atrial fibrillation (AF).
- Participated in support of a research project entitled "Atrial Fibrillation Screening Using a Handheld ECG Device." Results from the Heart and Stroke Foundation "Be Pulse Aware Campaign" to be submitted for presentation at the 2013 Canadian CardioVascular Congress in Montréal, Canada.
- Selected as a preferred technology for ECG screening in a national research project. Applied for funding under the Centres for Health Initiatives Research entitled "Identification of *Actionable* Atrial Fibrillation in the Community: An initiative from the Canadian Atrial Fibrillation-Stroke Prevention Network." The HeartCheck™ ECG Monitors are intended for use in 25 pharmacy and primary care physician sites to screen 8,000 people and the use of the HeartCheck™ PEN ECG in a head-to-head comparison to 30 days of event loop recorder monitoring.
- Received mention in July 2013 edition of *CONGENITAL CARDIOLOGY TODAY: Timely News and Information for BC/BE Congenital/Structural Cardiologists and Surgeons*. Article can be found at [www.congenitalcardiologytoday.com/index\\_files/CCT-JUL13-NA.pdf](http://www.congenitalcardiologytoday.com/index_files/CCT-JUL13-NA.pdf).
- Received mention in consumer blog sites: <http://20plus30.blogspot.co.uk/2013/07/doctor-google-and-nurse-pharmacy.html> and [www.livingwithatrialfibrillation.com/the-heartcheck-pen-review-cardiocomm-solutions](http://www.livingwithatrialfibrillation.com/the-heartcheck-pen-review-cardiocomm-solutions).

## Potential Milestones

### *Near Term (2013)*

- CardioComm Solutions is working with an independent company specializing in the development and integration of firmware- and software-based algorithm technologies, named Monebo, to incorporate an algorithm that will allow almost near-time feedback (auto-triage) to HeartCheck™ PEN ECG device clients. In addition, an algorithm for ECG interpretation from Monebo will likely be incorporated with the Company's GUAVA II FDA clearance submission in addition to the already incorporated Leuven Algorithm.
- The Company expects to experience continued expansion of its SMART Monitoring services as it plans for additional SMART Monitoring revenue-generating opportunities from new consumer ECG recording devices and new biomarker measuring products (e.g., pulse oximetry, blood pressure, and blood glucose).

### *Longer Term (Through 2016)*

- The Company has stated its goal of selling one million HeartCheck™ PEN devices and conducting three million ECGs readings through its own SMART Monitoring services as well as franchising the SMART Monitoring ECG call center services.
- CardioComm Solutions plans to launch its multi-device, multi-biometric monitoring solutions globally in both the consumer and the prescription markets following the previously established HeartCheck™ ECG distributor channels.
- The Company intends to advance development of ECG monitoring, wearable devices with GSM communications transmitting technology and complete a \$4 million pre-placement financing and joint venture deal ahead of an IPO of a newly-formed U.S.-based subsidiary, called iMedical. From this amount, roughly \$1.3 million is expected to come into CardioComm Solutions for services rendered.



## Intellectual Property

### Patent-Pending SMART Monitoring Service Technologies

As announced on May 9, 2013, the Company filed for U.S. and Canadian patents for use of its technologies in the automated, software-enabled and server-based unlocking of OTC, consumer-based, bio-monitoring devices. Under the U.S. and Canadian patent applications, filed on May 6, 2013 and May 8, 2013, respectively, the Company is permitted to apply the statement “Patent-Pending SMART Monitoring Service Technologies” in its corporate materials until the application process has been completed. The patent-pending SMART Monitoring service technologies are intended to enable, or unlock, personal health monitoring devices that display biosign wave forms and images and can be used for remote access interpretation. Until now, such devices were available only under physician prescription.

The patent application scope covers more than ECG-based technologies. These patent applications are intended to extend to any biosign image management solutions involving consumer-based, home, or remote access monitoring of medical devices capable of recording, displaying, and/or transmitting a biometric measure or image. These patent applications have multiple claims involving the unlocking of an OTC product for biosign viewing and receipt of interpretive reports under the control of a combination of device-unique and user-unique identifiers, cross matched on a robust and centralized monitoring server system. Through the use of these specific protocols confirming receipt and viewing of medical reports by physicians and consumers, the equivalent of a doctor/patient relationship is established. Once established, the monitoring server updates the device record of the biosignal recorder to indicate that it is eligible for biosign signal viewing (unlocking).

### Trademarks

In addition to the filing of the U.S. and Canadian patents, as described above, the Company is also in the process of attaining trademarks on GlobalCardio™ and has just confirmed Canadian trademark rights for HeartCheck™ on devices and HeartCheck™ ECG monitors in printed and electronic media.

## Company Leadership

CardioComm Solutions is led by a skilled management team with expertise in the medical technology and clinical research markets, software and hardware design, corporate finance, and business development. Biographies of these individuals are provided below.

### Management

#### *Etienne Grima, M.Sc., CHE, Chief Executive Officer*

Mr. Grima has over 22 years of experience in basic and clinical research administration, business development, and strengthening corporate performance. He joined CardioComm Solutions' Board of Directors in December 2006. In January 2008, he was requested to serve as the Company's chief financial officer (CFO) and corporate secretary during a period of organizational restructuring. In May 2010, he accepted the position of chief executive officer (CEO). Mr. Grima has also held the position of chief operating officer and financial officer for the Canadian Heart Research Centre (CHRC) since its start in 1996 when he co-founded it with Anatoly Langer, and a similar role in MD Primer Inc. since 2004. In all his roles, Mr. Grima continues to oversee operational and financial performance, contract and budget negotiations, financial reporting, and the evaluation of strategic partnerships and long-term growth opportunities. Prior to the CHRC, he managed the St. Michael's Hospital (SMH) Health Sciences Research Centre in Toronto. Mr. Grima guided SMH to become the fastest-growing University of Toronto-affiliated research center between 1994 and 1997, acting as the signing officer on 350 externally funded clinical and basic research budgets, and overseeing the design, construction, and maintenance of 27,000 square feet of clinical and basic research laboratories. During his tenure, he developed a detailed understanding and methodology of the successful performance of clinical research within a hospital environment and became a member and Accredited Health Science Executive of the Canadian College of Health Service Executives. Mr. Grima's educational background was rooted in his interest in biology and he completed his academic career with an emphasis on human physiology, toxicology, and zoology, graduating from University of Toronto with high distinction in 1984. Mr. Grima completed graduate studies in 1986 at the University of Toronto with a master's degree from the Faculty of Medicine, Department of Physiology, Center for Research in Neurodegenerative Diseases, and served as a peer reviewer for research publications and grant applications.

#### *Wendy Hsieh, Chief Financial Officer*

Ms. Hsieh showed an interest in accounting while studying in college. After completing a degree in economics, she pursued an accounting degree at York University. While attending York University, Ms. Hsieh took her first position working as a junior clerk with Donald Foreman Chartered Accountant. In 1999, she was recruited by CHRC as an accountant. Over the next six years, Ms. Hsieh progressed to become the manager of the finance department, where she managed a team of six people. In September 2007, Ms. Hsieh was conferred the degree of certified general accountant at both national and Ontario levels. In 2007, she was offered the position as comptroller of CardioComm Solutions, where she supported the CFO in the financial transactions of the Company. In 2010, Ms. Hsieh became CFO for CardioComm Solutions. Today, she still continues to support the CHRC as the manager of the finance department. Ms. Hsieh's strengths include managing job accounting reporting requirements and inventory control with respect to the performance of two different companies—one involved in software and hardware supply and the second in clinical research and education.

#### *Wade Barnes, Chief Technology Officer*

Mr. Barnes is experienced in specialized software and hardware design for several different industries, including robotics, transport trailer manufacturing, aquaculture, road traffic, information technology, and healthcare. He started working in an engineering capacity before graduating with honors from Camosun College's Computer Engineering Technology program in 1997. Since starting with CardioComm Solutions in July 2002, his focus has been engineering technology for the healthcare industry. Mr. Barnes is responsible for product development and information technology at CardioComm Solutions.

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*Mona Palfreyman, Director of Customer Support and Quality Assurance*

Ms. Palfreyman has over 10 years of experience in the medical technology industry, including experience in client support, technical training, and corporate operations. Her focus is on corporate success through a high level of quality client relationship management and corporate visioning. As the direct link between corporate headquarters and the Victoria office, Ms. Palfreyman works to ensure corporate sustainability and client satisfaction. She started her career at CardioComm Solutions as part of the quality assurance and customer support team, playing a key role in advancing the reputation of CardioComm Solutions by providing superior customer support. The knowledge gained by working onsite and offsite with many of CardioComm Solutions' customers has provided Ms. Palfreyman with a solid foundation to lead the Company's team in providing the products and services that its customers need in order to meet demands of their respective customers and patients.

**Board of Directors**

*Etienne Grima, M.Sc., CHE, Chief Executive Officer*

Biography provided on page 16.

*Anatoly Langer, M.D., M.Sc., FRCPC, FACC, Chairman of the Board*

Dr. Langer graduated from the University of Manitoba in 1982 and completed internal medicine and cardiology training at the University of Toronto in 1987. He is a fellow of the American College of Cardiology and Canadian Royal College of Physicians and Surgeons. After two years as a Heart and Stroke Foundation Research Fellow, he became a director of the Coronary Care Unit at St. Michael's Hospital in Toronto, Canada. In 1996, Dr. Langer founded the Canadian Heart Research Centre (CHRC), with the goal of improving the care of cardiovascular patients through clinical trial research, physician and patient education, and information sharing. Dr. Langer has over 250 peer-reviewed publications, abstracts, and book chapters. His areas of interest and research include pathophysiology and management of acute and stable coronary syndromes, as well as treatment and prevention of cardiovascular disease. More recently, Dr. Langer has been a participant in the development of EHRs, web-based applications for management of vital data and telemedicine. The CHRC is also in the midst of organizing a QT prolongation study ([www.chrc.net/qtstudy](http://www.chrc.net/qtstudy)). Since becoming a chairman of the Board of Directors at CardioComm Solutions, Dr. Langer has championed the innovation for office- and home-based data acquisition and early disease management algorithms. Currently, Dr. Langer is a professor of medicine at the University of Toronto and a staff cardiologist at St Michael's Hospital. He is a chair of CHRC and has extensive research experience in the conduct of clinical trials with over 15 years of experience in protocol design, study coordination, and data management.

*William E. Smith, MBA, C.Eng, CITP*

Mr. Smith began his career as a systems engineer at IBM Canada, where he was sent to Japan in 1972 to provide information management systems (IMS) manufacturing expertise to Toyota. In 1990, he underwent rigorous TV training in San Francisco and was live on CNN, Good Morning America, and various live television talk shows in Silicon Valley. In 1990, Mr. Smith was invited to be a keynote speaker at PAC Bell's annual corporate convention, where he spoke on the future of home automation technology. He was a guest speaker at Seybold's first "Digital World" conference in Beverley Hills in 1991, where he spoke on the future of the digital highway and first proposed the revolutionary digital highway to PAC Bell and an audience of Silicon Valley high-tech personalities. As the founder of CardioComm Solutions in 1989, Mr. Smith was nominated as Canadian Entrepreneur of the Year in 1995. In 2000, as Microsoft's EMEA finance industry manager, Mr. Smith traveled extensively throughout the EMEA region and was guest speaker at a large number of external conventions. He completed two years at Microsoft as EMEA finance industry manager for Microsoft Europe, Middle East, and Africa, and left Microsoft in May 2001 to take the position of chief operating officer with ICT, a startup company focused on core banking opportunities in financial services. In February 2004, Mr. Smith was invited by Royal Roads University of Canada to teach a two-week pre-MBA boot-camp course to 55 mature learners in Tehran, Iran.

*Yury Levin, CA*

Mr. Levin graduated from the faculty of business administration at York University in 1980 and subsequently articulated with Deloitte. He received the Chartered Accountant (CA) designation in 1983. Mr. Levin started and operated an independent accounting firm for 13 years. Subsequent to exiting public practice, Mr. Levin was president of a firm distributing Canadian pharmaceutical products and medical equipment in Europe. Currently, Mr. Levin is president of a manufacturing and distribution company in the construction industry. He joined CardioComm Solutions' Board of Directors in December 2008.

*David Newman, M.D., FACC, FRCP(C)*

Dr. Newman is an associate professor on the faculty of medicine at the University of Toronto. His main area of clinical activity and research is adult clinical cardiac electrophysiology. Dr. Newman received a B.Sc. and M.D. at Dalhousie University, followed by training in internal medicine and cardiology at the University of Toronto. He went on to post-graduate training in cardiac electrophysiology at the University of California, San Francisco and Stanford University before returning to Toronto. Dr. Newman currently works in the Toronto community and is also a member of the arrhythmia service at Sunnybrook Hospital medical center, a University of Toronto teaching hospital. In his practice, Dr. Newman has had experience with all forms of invasive and non-invasive arrhythmia and general cardiac investigations. He was among the first clinicians in the Toronto area to use loop recording devices in clinical practice. His research areas include health-related quality of life in arrhythmia research, cardiac electropharmacology, device management, and catheter ablation. Dr. Newman has expertise in areas of signal acquisition, interpretation, and clinical use of ambulatory ECG information across a variety of patient groups and indications. He has a large practice in community-based primary care cardiology and arrhythmia referrals, while maintaining a significant academic and clinical presence in the academic teaching hospital arena. This dual expertise enables him to be an important advisor to CardioComm Solutions as the Company seeks to make its products available to the larger general cardiac as well as specialist community.

*Simi Grosman, MBA, Consultant and Board Member*

Mr. Grosman is a seasoned senior executive with over 30 years of experience in business management, including sales, marketing, and business development. His relationship and communication skills result from a unique blend of professional expertise with a wide range of local and international companies—ranging from start-ups to large multinationals and everything in between. For the past 10 years, he has built his knowledge and reputation in the mobile industry, providing industry leaders with guidance and assistance in achieving their objectives. Mr. Grosman has headed up sales, marketing, product management, and professional services organizations ranging in size from 5 to 100 people for large multinational companies, including NCR, AT&T, and Accuris Networks, as well as industry start-ups. He has been a part-time professor at the Humber School of Global Business Management and International Marketing; has been executive member on several public and private institutional boards; and is currently sharing his understanding of the various disciplines related to mobile marketing with a number of local and international start-ups. His expertise in mobile marketing, business development, strategic planning, and stakeholder relations is combined with a broad understanding of various technology platforms and applications. He was a prior Board member at Intertainment Media Inc.

## Core Story

### CARDIOVASCULAR DISEASE

As the leading cause of death in the U.S. for both men and women, cardiovascular disease is a highly prevalent medical condition where there is a significant need for intervention by the medical community. Heart disease affects people of every race and geography and is not only responsible for the greatest mortality burden in the U.S., it is also the leading cause of death worldwide (Source: the World Health Organization [WHO]). Heart disease can present in many different forms, whether congenital (existing at birth) or brought on by environmental/lifestyle factors, such as smoking or an unhealthy diet. Regardless of how it arises, the most common fatal outcomes of cardiovascular disease are heart attacks and strokes. Each year in the U.S., there are approximately 715,000 heart attacks and 795,000 strokes (Source: the Centers for Disease Control and Prevention [CDC]). For many of these individuals, there is little to no warning that they are about to suffer a heart attack or stroke, which is a major factor contributing to the high fatality rate of cardiovascular disease. Heart attacks, in particular, are often sudden and are associated with symptoms that many people fail to recognize as they are easily mistaken for routine feelings (as listed in Figure 3).

Figure 3

#### SYMPTOMS OF A HEART ATTACK

- Pain or discomfort in the jaw, neck, or back
- Feeling weak, light-headed, or faint
- Chest pain or discomfort
- Pain or discomfort in arms or shoulder
- Shortness of breath

*The chances of surviving a heart attack are greater when emergency treatment begins quickly.*

Source: CDC <[http://www.cdc.gov/heartdisease/heart\\_attack.htm](http://www.cdc.gov/heartdisease/heart_attack.htm)>.

It has been found that a person's greatest chances of survival and avoiding long-term heart damage occur when emergency treatment is administered early on (Source: CDC). On the contrary, roughly 50% of deaths from a heart attack happen before the patient has a chance to seek help. Likewise, strokes kill someone in the U.S., on average, every four minutes, and in cases where the patient survives a stroke, there is often still a subsequent long-term disability that may never heal.

CardioComm Solutions' products are targeted at helping improve outcomes for people who are prone to or who are suffering from cardiovascular diseases. As detailed on pages 23-37, the Company's electrocardiogram (ECG) telemetry solutions enable remote monitoring for patients who have been diagnosed with either atrial fibrillation (AF) or another cardiac arrhythmia, or who are at risk for any of the following conditions: heart attacks, cardiomyopathy, high blood pressure, congenital heart defects, heart valve disease, coronary heart disease, sleep apnea, and heart failure, among other afflictions. By providing accurate, immediate cardiac data, patient monitoring technologies, such as those available from CardioComm Solutions, could increase the likelihood of individuals surviving a severe cardiac event, like a heart attack or stroke.

### Cardiac Arrhythmias

CardioComm Solutions' products may have considerable market opportunity for individuals who are known to have a cardiac arrhythmia—a condition where the heart beats too fast, too slow, or irregularly. While some arrhythmias can be harmless, others may also cause poor blood flow throughout the body or clots that are in danger of cutting off blood flow to the brain, which can cause a stroke. Additional symptoms from an arrhythmia include shortness of breath, wheezing, weakness, dizziness, lightheadedness, fainting, and chest pain or discomfort—any of which could also be a signal of a potentially dangerous heart rhythm. Patients with a cardiac arrhythmia are advised to seek urgent medical attention if they suddenly or frequently experience any of those symptoms, as abnormal heart rhythms are leading causes of **sudden cardiac arrest** and **sudden cardiac death**. Real-time diagnostic monitoring of patients' heart readings could alert patients as well as caregivers of critical changes in heart rhythms.

In the general population, approximately 50% of individuals have a cardiac arrhythmia of some form, most of which manifest only as benign heart palpitations (Source: the University of Minnesota). However, over four million people in the U.S., most of whom are over age 60, experience critical heart arrhythmias that require close monitoring and often require medical care (Source: *U.S. News and World Report*, 2009). Figure 4 summarizes the primary risk factors/causes of arrhythmias, noting that as the prevalence of many of these factors increases, so too does the numbers of people living with arrhythmias. For example, there are almost two million new cases of diabetes diagnosed each year (Source: the American Diabetes Association).

Figure 4  
POSSIBLE CAUSES OF AN ARRHYTHMIA

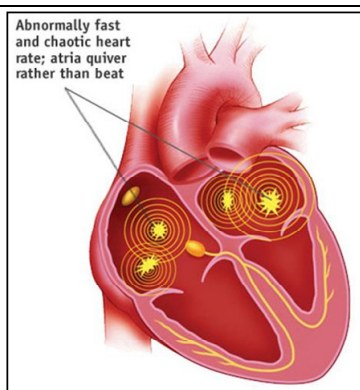
- |   |                       |
|---|-----------------------|
| ▪ Heart attack (either a prior heart attack or one in progress)   | ▪ High blood pressure |
| ▪ Changes to the heart's structure, such as from cardiomyopathy   | ▪ Diabetes            |
| ▪ Blocked arteries in the heart (coronary artery disease)         | ▪ Stress              |
| ▪ Congenital heart disease (heart abnormality present from birth) | ▪ Electrical shock    |
| ▪ Overactive thyroid gland (hyperthyroidism)                      | ▪ Air pollution       |
| ▪ Smoking/Drinking too much alcohol or caffeine/Drug abuse        | ▪ Sleep Apnea         |
| ▪ Medications/Dietary supplements/Herbal treatments               |                       |

Source: Mayo Foundation for Medical Education and Research.

Going forward, the size of the population that could benefit from CardioComm Solutions' ECG telemetry devices is likely to continue to increase as nearly two billion people over age 60 are expected to be alive worldwide by 2050—almost triple the 700 million people over 60 who were alive in 2009 (Source: *World Population Ageing 2009* from the United Nations' Department of Economic and Social Affairs, Population Division). As the global population ages, consumers will likely increasingly seek out the products and technologies that can help them live longer and in more comfort, as further described on page 22 under *Remote Cardiac Monitoring Market*.

### Atrial Fibrillation

Figure 5  
ATRIAL FIBRILLATION



Source: Boston Scientific Corporation.

The most common type of arrhythmia is atrial fibrillation (AF) or “A fib,” which occurs when the heart's upper chambers (the atria) fluctuate chaotically and very quickly (as illustrated in Figure 5). Versus a normal resting heart rate of 60 to 100 beats per minute, people who have atrial fibrillation can have heart beats ranging between 300 and 600 beats per minute. This can be a serious condition, particularly in older adults. The presence of an A fib arrhythmia doubles a patient's risk of cardiac death and increases the risk of stroke by as much as four to five times (Source: the American Heart Association, May 2012). Perhaps consequently, mortality from A fib (as either the primary or an underlying cause of death) has been increasing for the past two decades (Source: the CDC's “Atrial Fibrillation Fact Sheet,” February 2010). As a result, there is an unmet medical need for improved monitoring of heart performance among this high-risk patient population, which CardioComm Solutions believes it can effectively serve.

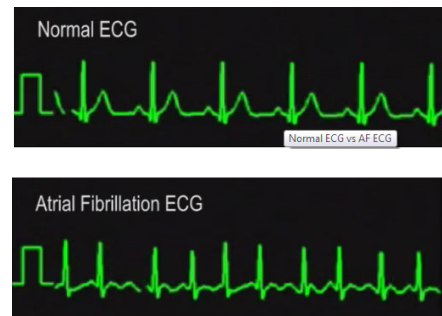
Approximately 2.7 million people in the U.S. today are living with AF, which is likely to expand as the population ages and, as a result, could become more common in older adults (Source: the American Heart Association, May 2012). For example, people over age 40 have a 25% chance of developing AF (Source: WebMD, Inc.). Accordingly, by 2050, it is estimated that as many as 12 million people in the U.S. may have the condition (Source: the CDC's “Atrial Fibrillation Fact Sheet,” February 2010).



## Cardiac Monitoring

AF is diagnosed and monitored using electrocardiogram (ECG) tests. An ECG measures the electrical activity of the heart that causes it to beat and pump blood throughout the body. It is very useful in understanding a person's overall heart health because it can provide information to learn of, or potentially prevent, different types of heart disease, including serious or lethal arrhythmias. Essentially, the ECG shows how fast a person's heart is beating, whether the rhythm of one's heartbeat is steady or irregular, and the strength and timing of electrical signals as they pass through each part of the heart. Figure 6 presents a normal ECG versus one of a patient with AF.

Figure 6  
 NORMAL ECG VERSUS PATIENT WITH ATRIAL FIBRILLATION



Source: CardioComm Solutions, Inc.

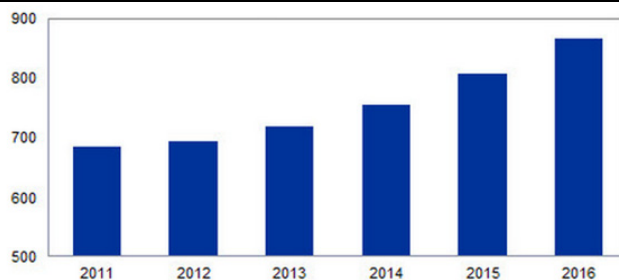
There are various types of ECG machines and devices on the market today. Each works essentially the same way in testing for heart rate abnormalities. The primary differences between devices are determined in the amount and type of information they gather, how they process the information, how they display the results, their portability, and their usability. A brief overview of the main types of ECG devices is provided as a frame of reference to the discussion of CardioComm Solutions' remote monitoring ECG technology.

- An ambulatory ECG records the electrical activity of a person's heart while performing usual activities and outside of a medical setting. These monitors are referred to by several names, including ambulatory ECG or EKG, **Holter monitoring**, 24-hour ECG, or **cardiac event monitoring**. While Holter ECG devices have been traditionally used most often to monitor heart irregularities over a 24- or 48-hour period, these devices are limited in the number of events they can detect. This is because many heart problems become noticeable only during activity, such as exercise, eating, sex, stress, bowel movements, or even sleeping.
- In contrast, remote cardiac monitoring devices (as detailed in the following section), which can be worn for longer periods of time, increase the likelihood of observing an abnormality because continuous 24-hour recording is more likely to detect any abnormal heartbeats occurring during these activities. As a result, such newer types of technologies involving telemedicine have made it possible to provide assistance to a greater population of patients. Today, through remote monitoring by means of wearing a cardiac event monitor equipped with wireless technologies, a monitoring center or physician can be alerted when a patient is in need of help, perhaps even before he/she experiences any noticeable cardiac symptoms. With such technology, call centers and physicians are able to directly contact the patient or, if necessary, dispatch assistance immediately through the use of global positioning system (GPS) technology. This can be likened to a scenario in which a patient is walking down the street and an ambulance pulls up beside them and says "get in, you are about to have a cardiac event."

If monitored accurately and treated properly, it is possible to live a healthy life with AF without serious or life-threatening complications. In contrast, foregoing heart readings and ignoring signs can increase patients' risks for developing blood clots, strokes, and heart failure. In addition, since not everyone experiences symptoms of AF, devices like those from CardioComm Solutions, which can detect dangerous heart rhythms even when patients are asymptomatic, are very important and can prove to be life saving.

## Remote Cardiac Monitoring Market

Figure 7  
FORECAST OF U.S. MARKET FOR REMOTE CARDIAC MONITORING SERVICES



Source: IHS InMedica Research, February 2012.

The U.S. leads the world in spending for remote cardiac monitoring. According to new research from iSuppli Corp., part of global information provider IHS Inc. (IHS-NYSE), this market had a value in the U.S. of \$686 million as of 2011, which is forecast to expand by 27% to reach \$867 million in the U.S. during 2016 (Source: IHS iSuppli's March 4, 2013, press release). Figure 7 illustrates anticipated growth in value of the remote cardiac monitoring market.

## Demand for Reduced Healthcare Expenses and Better Patient Care

Growth in the remote cardiac monitoring market is being fueled by a rise in life-altering chronic diseases requiring more frequent or continuous monitoring, such as for patients with serious cardiac arrhythmias, as well as a demand by patients, physicians, and payers alike for more affordable healthcare. The cost of healthcare has recently come under intense scrutiny in the U.S., leading to the passage of new legislation aimed at reform (e.g., the **Affordable Care Act**), adoption of electronic medical records (EMRs) and other digital systems to streamline operations and reduce the cost of care, and a much greater focus on the preventive and early detection strategies that can reduce the burden of treating chronic diseases. Spending on treatment and care for chronic diseases—primarily heart disease, stroke, cancer, and diabetes—accounts for approximately 75% of the more than two trillion dollars spent on healthcare in the U.S. each year (Source: CDC, April 2011).

### Patients and Physicians

One of the ways in which healthcare providers seek to better manage these expenses is to assemble data on the growing number of cardiac patients outside of the hospital environment by using telehealth devices. Remote monitoring allows physicians to observe a larger number of patients with fewer resources (such as time, staff, beds, etc.). As well, remote devices not only save patients and physicians the time and costs associated with a hospital visit for routine diagnostics, but they can enable physicians to observe patients over extended periods of time to obtain a more accurate and prolonged depiction of cardiac function in daily life. This is also beneficial for providers who seek to maintain close ties with their patients in between visits or during follow-up care. Furthermore, by enabling around-the-clock monitoring of vitals for patients who may appear asymptomatic for others up until the point of a severe cardiac event, telehealth technologies may improve patient outcomes.

### Payers

As a result of these benefits, the U.S. Medicare system and many other insurance companies offer reimbursement for cardiac telemetry devices in order to incentivize healthcare providers to use these technologies as a method of enabling early detection of cardiac disease, with the ultimate goal of reducing treatment and hospitalization costs in the future. Among Medicare recipients alone, AF (one of CardioComm Solutions' targeted patient populations for its ECG devices) is responsible for more than 1.7 million hospitalizations per year (Source: *Critical Care Nurse*, Vol. 30, No. 6:68-78, December 2010). The cost of hospital care, in- and out-patient physician care, and medications contributes to an estimated annual cost of treating AF of over \$6.65 billion (Source: the CDC's "Atrial Fibrillation Fact Sheet," February 2010). Remote monitoring has been widely credited with reducing hospital readmission rates, which is becoming a major focus for healthcare providers as insurance companies and Medicare begin to levy readmission penalties on providers (Source: IHS InMedica's January 21, 2013, press release).

## ECG Telemetry Sector

Within the remote cardiac monitoring market, the ECG telemetry sector is forecast to grow at a compound annual growth rate (CAGR) of 4.4% from 2012 to 2018 as a result of increasing sales of such products for home care purposes (Source: Market Research Reports' *ECG Telemetry Devices Market - Global Industry Size, Market Share, Trends, Analysis and Forecasts 2012-2018*). Globally, sales of ECG telemetry devices could reach as high as \$1.25 billion by 2017 driven by an aging global population, increasing incidence of cardiovascular diseases, and technology innovations that are expected to boost adoption (Source: Global Industry Analysts, Inc.'s March 16, 2012, press release). Beyond sales of ECG devices, the market for ECG management systems is expected to experience an even greater growth rate over the next several years as hospitals strive to increase efficiency, reduce costs, and improve patient care and diagnoses by connecting ECG devices to a centralized database. In its report *The World Market for Diagnostic Cardiology Devices and Remote Cardiac Monitoring Services – 2012*, IHS InMedica forecast global ECG management system market revenue of \$139 million by 2016, an 18% increase over 2011 (Source: IHS Inc.'s March 28, 2013, press release).

## CARDIOCOMM SOLUTIONS' MOBILE MEDICAL MONITORING

As described on the preceding pages, the market for cardiac disease monitoring is vast with billions of dollars spent on devices to monitor patient's heart rates and ECG morphologies. CardioComm Solutions is an innovator of integrated solutions for information management and ECG signal acquisition and viewing in cardiovascular medicine and telemedicine. The Company has technologies that enable mobility in ECG management, allowing for remote cardiac monitoring by not only medical professionals but also by patients and consumers themselves—thereby transitioning the care into the patient's hands and allowing them to be connected to the proper facilities or cardiac monitoring centers 24/7. The Company's technology enables medical professionals and patients alike as well as clinics, hospitals, and call centers to quickly access and manage patients' cardiac information in a secure and reliable environment from anywhere in the world. The Company is compliant with several major quality and privacy standards, including ISO 13485, Health Protection Branch (Canada), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and has received FDA market clearance for its devices. An overview of the Company's integrated solution portfolio is provided in Figure 8.

Figure 8  
INTEGRATED SOLUTION PORTFOLIO

Devices	Software	SaaS/ASP	Services
<u>CardioComm</u>			
<b>HeartCheck™</b>	<b>GEMS™</b>	<b>GlobalCardio™</b>	<b>C4™</b>
- PEN	- Home	- 3 Lead	- Data Management
- Handheld ECG	- Air	- 12 Lead	- Triage
- Future Products	- HL7	- EMR	- Interpretation
- <b>GEMSTrack AF™</b>	- Lite		
	- Auto Attendant		
<u>Other Brands</u>			
<b>Third Party</b>	<b>Private Label</b>	<b>GUAVA™</b>	<b>Licensed</b>
- Vitaphone	- Philips		Automated Triage*
- MedNet	- GE Healthcare		
- MidMark	- TZ Medical		
- NorthEast			
- Cardiac Science			
- QRS			

\*future products

Source: CardioComm Solutions, Inc.

CardioComm Solutions is currently focused on targeting the consumer arrhythmia monitoring market, specifically with reference to atrial fibrillation (AF) detection (the most common cardiac arrhythmia). AF is the most widely experienced complication following heart surgery. Individuals with AF have a one in four chance of developing a stroke within four years, where 30% of those who have a stroke die, and for those who do survive, many experience a disability to some extent. As well, for those who survive a stroke, there is a high chance of experiencing another stroke. It is estimated that 70% of strokes can be prevented with a simple diagnosis and oral medication—where such diagnosis can come from event reporting ECG technologies that give physicians a greater understanding as to a specific patient's condition and thus allow the patient to attain proper medical care prior to an event occurring. CardioComm Solutions is leveraging its 14 years of medical experience in hospitals, call centers, and physician offices to bring this consumer-based technology to market.

## **PRODUCT OVERVIEW**

CardioComm Solutions has developed integrated solutions for cardiac information management, closing the loop between experiencing symptoms and receiving treatment. The Company's medically prescribed technology, which can be used for recording, observing, analyzing, and storing ECGs, allows patients' heart readings to be reviewed and interpreted by physicians over a virtual healthcare network in real time and with potentially life-saving speed. Patients who are suspected or known to have cardiac arrhythmias may greatly benefit from access to a monitoring service because when they are experiencing such events (and many times they are unaware of it), they can receive an alert. Through wireless technology and GPS assistance in locating patients, proper medical attention can be quickly dispatched if necessary. CardioComm Solutions' FDA-cleared and European Directives-approved products include the GEMS™ (Global ECG Management Systems)/GEMS™ Home and GlobalCardio™ EMR software, the HeartCheck™ ECG devices, as well as the Company's HeartCheck™ SMART Monitoring services, highlighted below and in greater detail in the accompanying section.

- **Software.** GEMS™ software enables a cardiologist to transmit, receive, and manage a patient's ECG from anywhere in the world through standard computers, wireless devices, enterprise networks, telephones, and/or the Internet. This enables the cardiologist to interpret a patient's ECG and assess their disease status anytime and anywhere, employing all available information, including prior conducted ECGs, and supports the proper integration with the various technologies that are used by monitoring centers or physicians' offices. The Company also markets GEMS™ as the GEMS™ Home edition, which is a consumer heart rhythm management solution based on the proprietary GEMS™ and uses the consumer-based HeartCheck™ PEN ECG device. GlobalCardio™ EMR enables bidirectional movement of data, including patient information, reports, and links to patients' ECGs from inside the EMR.
- **Hardware.** The HeartCheck™ brand includes the HeartCheck™ Handheld ECG Monitor for use in a medical setting, and the recently introduced HeartCheck™ PEN ECG device, which is the first FDA-cleared, handheld, over-the-counter (OTC), consumer-targeted ECG product that performs and displays an ECG without the requirement of prescription and through the establishment of a virtual patient/physician relationship.
- **Services.** HeartCheck™ SMART Monitoring enables individuals to have their HeartCheck™ PEN-recorded ECGs viewed, analyzed, and interpreted by a physician, ECG Coordinating Center, or both, over the Internet. This is a true telemedicine solution enabling remote access interpretation to be performed regardless of where a consumer or patient is located. These ECG-reviewing medical call centers exist in a partnership-type relationship with CardioComm Solutions as they employ technicians and physicians who can read and interpret an ECG within 30 minutes, 24 hours a day, 7 days per week, 365 days a year. When a client transmits the ECG, the technician and/or physician immediately reads the ECG and can determine what services are necessary—from recommending that the consumer go to the hospital or call their physician at their next opportunity to verify that the ECG reading appears normal. The patent-pending SMART Monitoring service ensures the interpreted results are returned to the registered consumer in compliance with all privacy and personal information protection regulations and laws. Until now, such devices were available only under prescription and were associated with high carrying costs to insurers and private payers. Now, with HeartCheck™ SMART Monitoring, along with the Company's HeartCheck™ PEN, CardioComm Solutions can provide a complete, cost effective, rapid full cycle of market-tested ECG monitoring services to patients and consumers alike.

## Software

Often overlooked when discussing medical monitoring is the software interface used by physicians to view and interpret medical data from individuals' ambulatory monitoring devices. CardioComm Solutions has been a provider of ECG management software solutions for the past 17 years. Using a patented and proprietary technology and ECG (signal) viewer, and by offering flexible open-ended workflow solutions, the Company provides technology that is compatible with the majority of the world's cardiac event monitors, including those intended for the home and telehealth markets. The Company's software products, which are marketed as GEMS™ and GlobalCardio™ EMR, are sold worldwide to hospitals, call centers, and physicians' offices through a combination of an external distribution network and CardioComm Solutions' North American-based sales team.

### *Global ECG Management System (GEMS™)*

CardioComm Solutions' software for cardiac event monitoring, called GEMS™, can easily receive and store patient information and ECGs as it has been designed to provide for the needs of busy clinics and healthcare professionals. GEMS™ is a management tool, which can be likened to an electronic medical record (EMR) or a personal health record, enabling physicians to track and assign interpretations of patient ECGs or medical notes. As well, it is believed to be a cost-effective alternative to currently used hardware receiving systems and can be easily installed on most desktop computers for use in tracking and storing comprehensive patient information, including enrollments, symptoms, medications, interpretations, device inventory, schedules, and a collection of reporting options for a variety of patient follow-ups and tests.

The other component to GEMS™, called GUAVA™, is CardioComm Solutions' ECG viewer software nested inside GEMS™, which takes signals from ECG recording devices and allows them to be viewed on a grid in a manner that is representative of the traditional ECG (such as described on page 21). The advantage of CardioComm Solutions' "grid" is that it is digital and can be expanded to look for particular sections of the waveform at higher magnifications. As well, it has electronic calipers that automatically calculate durations of different waves or waveform morphology and determines the presence of any duration differences.

CardioComm Solutions' software, which has been developed to be largely device agnostic, works with multiple manufacturers' ECG monitoring devices. It is classified as a medical device and delivers solutions for a variety of different workflows related to reading ECGs. Beyond its open architecture, other key features of GEMS™ include its detailed standard and custom reports, which can be posted to secure websites; its real-time ECG viewer, which can be distributed or licensed as a software development kit (SDK); its ability to be fully scalable (which makes it an application tool to both small clinic and large hospital scenarios); and its AutoAttendant™ module for computer-automated answering of event recorder transmissions (critical for improving efficiency and reducing staffing requirements). Figure 9 summarizes features and options available with CardioComm Solutions' GEMS™.

Figure 9  
GEMS™: FEATURES AND OPTIONS

- Assign and track event recorder inventory	- 24/7/365 customer service and support
- Custom list editor	- Full ECG recording, editing, and report tools
- Customizable physician notification (Fax, Email, Mail)	- HL7 interface compatible
- Upload reports to the Internet using the Report Upload utility	- Inventory management for Pacemaker transmitters
- Single or multi-user licensing available	- Pulse width marker display on TTM ECGs
- Custom reports, AA, Air and scheduler	- Complete follow-up history

*Source: CardioComm Solutions, Inc.*

AutoAttendant™ eliminates the need for a technician to manually receive ECGs transmissions one at a time and enables healthcare providers and independent diagnostic testing facilities (IDTFs) the ability to focus their resources on delivering patient care by permitting staff to work with many ECGs recordings after they are automatically received for ECG interpretation and determining the best course of action with each monitored patient. The AutoAttendant™ solution can manage any number of simultaneous, incoming ECGs which are then queued based on time received for review by the attending ECG technologist and/or physician. The result is a streamlined system for collecting large volumes of ECGs and a reduction in staffing requirements to manage the ECGs. Applicability for this software technology is within IDTFs, hospitals, and large cardiology practices, where arrhythmia monitoring services are performed.

CardioComm Solutions' GEMS™ and GlobalCardio™ (with the ECG viewer embedded within), are both cleared as Class II medical devices within North America, a characteristic that few ECG management software solutions offer. The FDA clearance of an ECG solution with an ECG viewer is required for credible ECG interpretations and has been the deciding factor in approvals for the purchase of GEMS™ and GlobalCardio™.

#### *GlobalCardio™ EMR Integration*

GlobalCardio™ EMR integrates with physicians' existing EMR systems and has been previously certified by Allscripts Healthcare Solutions, Inc. (MDRX-NASDAQ), as compatible and compliant software, enabling bidirectional movement of data, patient information, reports, and links to ECGs from inside the EMR. This integration makes technician and physician work more streamlined and efficient. Users need only sign-on once versus the need to log into multiple systems, and patient information from GlobalCardio™ is available via a link to GlobalCardio™ or through PDF reports uploaded from GlobalCardio™ into the EMR.

#### *GEMS™ Air (Live Wireless ECG Monitoring)*

In 2009, CardioComm Solutions developed GEMS™ Air as an add-on module to place on top of its base GEMS™ software. GEMS™ Air enabled the communication with wearable and Global System for Mobile (GSM)-enabled devices to monitor patients and communicate wirelessly, in real time, with monitoring services. The GSM-enabled devices may be of a one- or two-piece hardware configuration. A one-piece design incorporates the GSM (cellular) technology within the ECG monitoring device, as is used in TZ Medical, Inc. (described below) and Braemar products. Braemar is a subsidiary of CardioNet, Inc. (BEAT-NASDAQ), as described on page 41. Other manufacturers utilize a dedicated cell phone, programmed only to work in communication with the worn ECG monitors so that the ECG monitor itself may be smaller and not require additional CRTC certifications. Both configurations have their strengths and weaknesses related to ease of wearing, cost of manufacturing, and inventory management. Regardless of the hardware used, the ECG monitoring device is intended to be worn continuously, can automatically or manually be triggered to record the occurrence of an arrhythmia, and will monitor individuals in real time. Regardless of the technology, GEMS™ Air is compatible with both one- and two-piece versions and is currently only available for monitoring individuals under a prescription/medical model.

#### *TZ Medical, Inc. and Expansion into the Mobile Cardiac Telemetry (MCT) Market*

CardioComm Solutions is currently working on a Mobile Cardiac Telemetry (MCT) module for its GEMS™ software, with a goal of completing this product by year-end 2013. There is currently one original equipment manufacturer (OEM) of an MCT device, called TZ Medical, Inc. ([www.tzmedical.com](http://www.tzmedical.com)). TZ Medical is an OEM manufacturer of an MCT device focused on the electrophysiology (EP), cardiac, and critical-care markets. In February 2012, CardioComm Solutions and TZ Medical entered into a device integration and distribution agreement for the MCT ECG and arrhythmia management market.

Under this agreement, CardioComm Solutions is to integrate TZ Medical's new Aera CT™ MCT monitor into its proprietary GEMS™ software. The GEMS™ MCT offering, to be called GEMS™ Aera CT, is an extension of CardioComm Solutions' GEMS™ Air solution, as described above. The TZ Medical device is intended to have the capacity to work on other cellular networks. Combined with FDA-cleared software from CardioComm Solutions, the Company believes that it now has a solid template with which to introduce this device to its customers. TZ Medical's products and solutions can be found in hospitals, critical-care clinics, and medical offices around the



world. Ultimately, the goal is to enable MCT billing by smaller independent call centers in the U.S., which, coupled with a device from TZ Medical, may enable it to compete, or collaborate, with the four largest participants—CardioNet, Inc., eCardio Diagnostics, LLC, LifeWatch Corp., and MedNet Healthcare Technologies, Inc. (described under Competition [pages 41-42]).

MCT-enabled IDTF companies (typically smaller operations) must refer their current patient base to competitor IDTFs because the doctors who wish to have an MCT test performed cannot do so with these smaller groups—thus they are forwarding their revenue onto the larger companies. CardioComm Solutions' technology is intended to allow smaller companies to keep their revenue, while giving the Company a good and broad-based foothold in the U.S. CardioComm Solutions expects this could provide it with a large base for licensing its MCT technology and could enable the Company (along with the TZ Medical device) to conduct wireless ECG monitoring on a global platform. TZ Medical's corporate headquarters are located in Portland, Oregon, with sales and support functions throughout the nation.

### ***iMedical Inc.***

CardioComm Solutions announced that it has entered into a pre-placement financing and joint venture agreement ahead of an initial public offering (IPO) of its U.S.-based subsidiary, iMedical Inc. Under a brokered deal, equity shares in iMedical are expected to be issued to individuals in exchange for \$4 million in funding for development of a wearable, GSM-enabled ECG monitor. Through a joint venture between CardioComm Solutions and Toronto-based Sensor Mobility Inc., Sensor's GSM platform technologies and CardioComm Solutions' ECG viewing and wireless software management systems are being licensed to iMedical. Sensor Mobility states that it has a cellular platform that can be embedded into a device such that the device can work anywhere in the world on a platform that is cost effective, and can enable true global wireless monitoring. Within the joint venture, iMedical is to become an independently operated and financially autonomous organization, where core intellectual property assets of the parties will be utilized to develop an FDA submission-ready, prototype GSM ECG device and software system for market clearance in the U.S.

Initial investors have been identified, and it is expected that all seed funding could be received during 2013. According to CardioComm Solutions' March 11, 2013, press release, while no work is scheduled to start until the first \$1 million is raised, both CardioComm Solutions and Sensor Mobility are preparing for a summer deployment of dedicated resources for initiation of their respective tasks. Once a 510(k) FDA submission has been made, fundraising efforts will likely commence to fund the iMedical IPO, with the aim of raising at least five years of working capital. iMedical is expected to hire its own CEO. Due to its involvement in iMedical, CardioComm Solutions expects to recognize revenue from multiple opportunities, and will have a right of first refusal for bidding on all third-party-based software engineering contract work as it relates to ECG acquisition, management, and interpretation. CardioComm Solutions also expects to collect royalties from the licensing of its core GEMS™/GlobalCardio™/GUAVA™ software intellectual property and is to receive funds from any profit-sharing or payment of dividends as a shareholder.

Details of the financing include 20 million restricted iMedical common shares issued at a \$0.20 per share price for anticipated total gross proceeds to iMedical of \$4 million. Of the \$4 million intended to be raised, approximately \$1.9 million is to be paid to Sensor Mobility and \$1.26 million to CardioComm Solutions for providing corporate leadership, software development, device integration, and preparation of regulatory applications services. The proposed share allocations of iMedical following the financing are as follows: 20% to Phase 1 investors, 35% to both Sensor and CardioComm Solutions, and 10% to a share pool for assignment by the iMedical Board of Directors at its discretion for corporate purposes.

### ***Objectives***

The iMedical transaction is expected to provide the following opportunities for CardioComm Solutions:

- (1) allow another entity to employ CardioComm Solutions' software to develop global, wearable wireless devices, where CardioComm Solutions is providing the software and regulatory support and Sensor Mobility is providing the manufacturing for working with GSM and general packet radio service (GPRS)-based technologies;

- (2) bring funds into CardioComm Solutions, with \$1.3 million expected to be received for services rendered; and
- (3) make CardioComm Solutions a shareholder in iMedical, with Mr. Etienne Grima, CardioComm Solutions' chief executive officer, a member of iMedical's Board of Directors.

#### *Software Product Licensing Relationships*

CardioComm Solutions is becoming a preferred software provider of cardiac ECG management systems. Globally, companies are rapidly developing new cardiac monitoring technologies both for the consumer market as well as for prescribed in-hospital or physician-based use. Since software development is a costly and complex undertaking, many companies would rather outsource these efforts. CardioComm Solutions is being recognized among the ECG management software engineering markets, and it expects to continue to see manufacturers seek out its assistance with the intent of developing platforms to launch respective products for a variety of global ECG management and screening opportunities.

The Company has multiple-year licenses with Philips Healthcare, which uses CardioComm Solutions' ECG viewer. In addition, GE Healthcare sells a private-label version of CardioComm Solutions' GEMS™ software. CardioComm Solutions also has organizational software licenses for its GEMS™ software, including to Kaiser Permanente, Mayo Clinic, and the Sick Children's Hospital in Ontario. As well, CardioComm Solutions has stated that it is in discussions with Avery Dennison Medical (under Avery's name Vancive for medical products) as well as Polar Electro Oy regarding hardware integration opportunities. Figure 10 provides a summary of these relationships.

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Figure 10  
MEDICAL CREDENTIALING

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- Multi Year Licenses
  - Philips Healthcare – Inside (Raytel) – ECG Viewer
  - General Electric Healthcare – OEM – Hospital Sales – Private Label of GEMS™
- GEMS Software Installations
  - Kaiser Permanente, Mayo Clinic – GEMS™
  - Sick Children's Hospital (Ontario)
- Hardware Integration Opportunities
  - Avery Dennison Medical (Vancive)
  - Polar Electro Oy

*Source: CardioComm Solutions, Inc.*

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#### *Potential Product Extensions*

In addition to being in the process of upgrading its GEMS™ software, CardioComm Solutions is also upgrading its ECG viewer technologies—currently called GUAVA™. This project is on track to be completed by year-end 2013. As well, the Company is positioning to have GUAVA™ approved separately and as part of its GEMS™ applications. Specifically, the Company seeks to receive FDA clearance for its ECG viewer as its own medical device—to be called GUAVA II—using a 510(k) application with the FDA. By re-writing GUAVA™, CardioComm Solutions seeks to convert it to become a multiple bioscience/biometric monitoring device with interpretation capabilities, perhaps able to monitor up to 10 channels—such as glucometers, spirometers, weight scales, thermometers, and any other biometrics used in either an OTC or prescriptive fashion—with the goal of building one software platform that can measure multiple biosigns from multiple device manufacturers, which CardioComm Solutions believes will be of significant interest in disease prevention management. Ultimately, CardioComm Solutions' device-agnostic approach may make it possible for the Company to introduce a cost-effective solution for consumers to monitor multiple parameters with only one platform—expanding its reach into the growing disease prevention and home healthcare markets.

In seeking FDA clearance for its own medical device using the FDA's 510(k) application process, CardioComm Solutions has responded to the FDA's questions and is in a 90-day review cycle. At the date of this report, the Company had entered a second review with the FDA, which could be completed by the end of July 2013. GUAVA II, if approved, is expected to become CardioComm Solutions' next step into the multiple biosign monitoring market. Currently, call centers may have two to three types of ECG monitoring solutions, just for ECGs. The goal for CardioComm Solutions is for its GEMS™ software to be able to accommodate all monitoring, ultimately, having other software solutions that would look at correlating glucose or asthma readings, etc., where it will only be necessary to operate one program instead of multiple programs and so that companies that make hardware can manufacture it to pair with CardioComm Solutions' software. CardioComm Solutions seeks to modify the viewer to perform multiple biosigns without needing additional FDA clearances on GEMS™ and GlobalCardio™.

Because CardioComm Solutions' technology is device agnostic, it may offer the ability to employ any device, regardless of whether it is enabled via the Company's software. The Company has stated its intent to only enable devices that are of superior quality, are FDA- and Health Canada-cleared, CE marked, and where CardioComm Solutions will benefit from the sale or use of those devices. The Company further expects to enter the sports and hard-labor market as it looks to provide effective monitoring tools for people who are active at the time of monitoring, such as during sports training. Furthermore, the Company has reported that it is involved in talks with government and community medical authorities on enabling remote and mobile monitoring technology. In addition, CardioComm Solutions is focused on a patent application in the U.S. and Canada for the process of using Internet-based communication to unlock devices to convert them into heart rate and ECG monitors. Importantly, even if the Company proves unsuccessful in the application process, it would still prove useful as it holds back the market for doing so for at least two years during the pending process.

Ultimately, CardioComm Solutions seeks to enter diverse biometric markets based upon enabling its GEMS™ software to read multiple devices. As well, since the Company already sells and distributes other devices, adding more call centers beyond its existing one to accommodate demand from these biometric markets could enable CardioComm Solutions to provide devices and software at cost, and organizations' overhead expenses could be reduced while expanding market access. Thus, the Company could leverage its expertise in global markets and perhaps develop a large contributing pool of reduced overhead so there would be profit sharing across the board.

## **Hardware**

In addition to its software platforms, as detailed on pages 25-29, CardioComm Solutions currently markets a prescription-based handheld heart rhythm monitor that can be unlocked to become an ECG monitor, similar to those devices only available with a physician's prescription. The Company is now focused on bringing to market its consumer-based handheld ECG monitor, employing its knowledge of ECG reading software solutions and the enabling of ambulatory monitoring of patients and leveraging these into a new and disruptive consumer product and technology. Much like how home blood pressure tests and pregnancy tests were introduced into home markets in the 1960s/1970s and, more recently, tests such as HIV and blood sugar monitoring for diabetics, CardioComm Solutions is tasked with educating consumers to accept cardiac ECG monitoring within a home environment. It is widely accepted today that an ECG is typically performed under a medical setting, whether it be in a physician's office, clinic, or hospital. However, given that the single most predictive indicator for cardiac arrhythmias is high blood pressure, and individuals can monitor their blood pressure at home, so too should they be able to monitor their heart rhythms via an ECG.

CardioComm Solutions identified a Chinese-based company called Beijing Choice Electronic Tech Co., Ltd. (ChoiceMMed [profiled on page 40]) that had developed an FDA cleared, prescription only, handheld ECG device called the MD-100. Several versions of this device were manufactured but none seemed to penetrate the medical market sufficiently. This handheld ECG device had been manufactured for roughly eight years and was available for sale worldwide prior to CardioComm Solutions taking an interest. CardioComm Solutions began working with ChoiceMMed, believing their product was a cost effective and promising ECG monitor that could be integrated with the Company's ECG management software that enabled mainstream ECG monitoring, physician prescribed devices to be used.

The Company foresaw that this device would have application in general practitioners' offices as well as in regions of the world that may not be able to afford a traditionally available ECG device, which was expensive, large, and required specifically trained individuals to use proficiently. Indeed, work cases where the HeartCheck™ device would have market penetration would be in situations where carrying heavy and bulky ECG machines may be impractical or budgets would preclude the deployment of any number of devices sufficient to meet unmet medical needs.

In discussions with the manufacturer, the Company then learned that a new enhancement to this type of handheld ECG recording device had been developed as a prototype. This prototype was a smaller "PEN"-like device measuring a compact 5.25 inches long, 1.25 inches wide, and 1 inch high, which could be easily carried and used to take and record an ECG at any time with little inconvenience. CardioComm Solutions had been investigating ways to access the consumer market, which was markedly larger than the finite hospital markets and was believed to be a relatively untapped market.

ECG signal processing represented the most difficult biosign to manage and this had been the sole focus of the Company since the 1990s. At that time, CardioComm Solutions sought to discover whether this could become a marketable consumer product, available without physician prescription. The work involved changing the device's firmware and integrating it with the Company's proprietary GlobalCardio™ software systems to enable the recorded ECGs to be uploaded from the device onto a Windows-based computer, whereby the device recorded ECGs could be managed, viewed, and presented to a physician to be interpreted and then provided back to the consumer.

After several months of working with the FDA to get an indication on how to move this forward, the Company was provided with a roadmap to get the "PEN" prescribed as a consumer product for use in the U.S. Subsequently, the Company submitted a 510(k) application on December 16, 2012. On December 22, 2012, CardioComm Solutions received clearance for use of the HeartCheck™ PEN ECG as a consumer product in the U.S. without any comments—signifying approval of the only OTC-cleared Class II medical device able to be sold as a heart rate monitor that can be converted into an ECG monitor and display ECG readings in real time and through a software program without physician direction. This would mark the first device available with such a clearance on the market to date.

ChoiceMMed is currently the designated manufacturer of CardioComm Solutions' diagnostic handheld ECG products. ChoiceMMed is also bringing to market other devices for which CardioComm Solutions will likely have the right of first refusal to integrate. ChoiceMMed has an extensive mobile sales force and CardioComm Solutions is in discussions with them to leverage that sales force to sell the HeartCheck™ brand of products, thus making ChoiceMMed a distributor to CardioComm Solutions. CardioComm would receive a licensing fee per device sold and would offer ChoiceMMed a percentage of SMART Monitoring service revenue from those devices sold through ChoiceMMed.

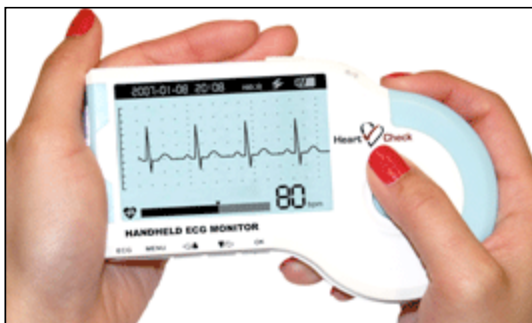
Since CardioComm Solutions holds the 510(k) FDA clearance for the HeartCheck™ PEN, ChoiceMMed cannot initiate sales of its own product. Further, without the Company's enabling of a ChoiceMMed-manufactured product (which is controlled at the device serial number level), only the Company's HeartCheck™ products are compatible with GEMS™ Home and the patent-pending SMART Monitoring service technologies.

#### *HeartCheck™ Handheld ECG Monitor*

CardioComm Solutions markets the HeartCheck™ ECG prescription device (as shown in Figure 11 [page 31]), as a portable, easy-to-use product that gives patients the ability to record and analyze their heart rhythms in a medical setting, such as while waiting for medical appointments or while attending to daily activities. Under such use, the person would be prescribed the device and its use would result in interpretive fees being applied for under a variety of reimbursement codes in both the U.S. and Canada. Patients would be provided a HeartCheck™ device after registering with the physician's office (for example, through the receptionist). Instruction would then be provided to the patient (available through the Company) on how to use the HeartCheck™ ECG Monitor and how to monitor their heart by taking a heart reading when symptoms are felt.

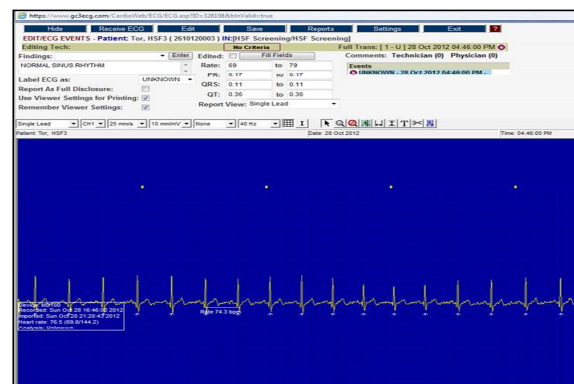
During its use, the patient must cover two metal plates on each side of the HeartCheck™ device and press the “Start” button to begin the heart rhythm evaluation (as shown in Figure 11). The device will display the real-time ECG waveform and providing the resultant heart rate (in beats per minute [BPM]) and display within 30 seconds. The device is able to store up to 200 ECG results for further review and analysis by a professional. When the patient finishes the analysis, the device may be connected to a PC with Internet access or returned to the physician’s receptionist who can connect the ECG monitor to a computer through the provided USB cable. The ECG data is then transferred to the Company’s patent-pending SMART Monitoring service called the CardioComm Solutions Coordinating Centre (“C4”). Within the C4 service, the transmitted ECG files are analyzed, and the completed interpretation may then be accessed and printed for review by the patient’s physician during a scheduled appointment or during a follow-up appointment (see illustration in Figure 12). The device can be used to aid doctors in quickly discovering and diagnosing heart disease, arrhythmias, AF, and other medical conditions associated with the heart. Patients may also upload ECGs from home through their own PCs, thereby facilitating ambulatory monitoring of a physician’s patients with little cost and complexity.

Figure 11  
HEARTCHECK™ ECG DEVICE



Source: CardioComm Solutions, Inc.

Figure 12  
HEARTCHECK™ HANDHELD ECG COMPUTER SCREENSHOT



Source: CardioComm Solutions, Inc.

### HeartCheck™ PEN

CardioComm Solutions’ newest device, which is an enhancement to its existing prescription-based ECG monitor is the HeartCheck™ PEN ECG (as shown in Figure 13), which was FDA cleared for consumer use on December 22, 2012. This device is the world’s first FDA-cleared, handheld ECG recording device that can be purchased by a consumer without the need of a physician prescription to allow consumers and patients to be able to view and print their own ECGs as part of their own health monitoring interests. With the HeartCheck™ PEN ECG device, patients can take heart readings the moment a symptom is felt—whether at home, the gym, or at the office. This is important as it affords individuals the ability to perform their own ECG monitoring at any time.

Figure 13  
HEARTCHECK™ PEN HANDHELD ECG DEVICE



Source: CardioComm Solutions, Inc.

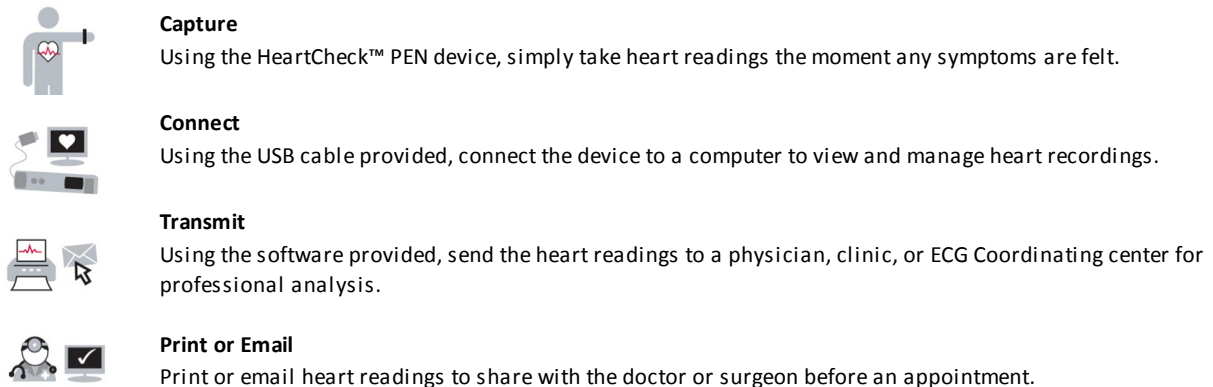
The device is portable, easy-to-use, and takes accurate heart readings anytime in only 30 seconds and can store 20 readings. Storing readings is important as, many times, people are symptomatic but then are not displaying the symptoms or ECG morphology they had previously experienced by the time they reach the emergency room or physician’s office. The Company has been securing customer feedback that indicates use of the HeartCheck™ PEN ECG device has assisted in confirmation of arrhythmias felt and recorded at home that were not present when with a physician. The use of the ECG reports, involving FDA-cleared devices and independently-cleared interpretive software, together with the ability to generate the resultant ECG tracing with a physician’s interpretation, has led to reduced cycle times in diagnosing underlying arrhythmias and thereby advancing access to appropriate medical interventions. This would be specifically true with the identification of AF.



The HeartCheck™ PEN, which retails for \$259, is initially being targeted at individuals who are experiencing cardiac arrhythmias and palpitations or those who are at risk for AF. There are over 2.3 million Americans diagnosed and living with AF. In addition to the at-risk or AF-positive population, the Company has seen interest for its HeartCheck™ PEN for use among athletes, senior citizens in their homes, nursing homes, and long-term care facilities. The HeartCheck™ PEN works with the Company's GEMS™ Home software (described on pages 25-26) and is part of the Company's HeartCheck™ and patent-pending SMART Monitoring service. The SMART Monitoring service solution utilizes a back-end similar to the software used in hospitals and call centers. Figure 14 provides a depiction of the HeartCheck™ device's functionality, where the device is used to capture an individual's heart reading, then is connected via USB cable to a computer to view the reading. The reading is transmitted to a physician, clinic, or ECG Coordinating Center for analysis and results are printed or emailed by a physician or surgeon prior to an appointment.

Figure 14

HEARTCHECK™ PEN HANDHELD ECG DEVICE: HOW IT WORKS



Source: CardioComm Solutions, Inc.

In 2012, CardioComm Solutions achieved five different device clearances for its HeartCheck™ PEN ECG device, including two FDA clearances:

- use of the HeartCheck™ PEN as a prescription product in the U.S.;
- use of the HeartCheck™ PEN as an OTC product in the U.S. (cleared by the FDA in five days);
- two clearances from Health Canada, which included approval for the HeartCheck™ Handheld ECG; and
- a CE Mark indicating the product's compliance with EU legislation and enabling the free movement of products within the European market.

CardioComm Solutions' Infrastructure for Internet-based ECG Transmissions

Anyone can use CardioComm Solutions' HeartCheck™ devices, have their data transmitted to the Company's data store, and have technicians or physicians review it. The Company has partnered with credible organizations through which to offer its SMART Monitoring service. In situations where data is generated in other countries, however, rules dictate that the data may need to be stored in the country where the data has been generated. Given the infrastructure the Company has in place with SunGard, CardioComm Solutions has available to it a globally expandable ECG services solution. The Company intends to develop a globally connected ECG monitoring service. To that end, CardioComm Solutions has successfully completed an audit (in 2013) with SunGard Availability Services, one of the largest co-location providers internationally and a provider of CardioComm Solutions' infrastructure for all of its SMART Monitoring, Internet-based ECG transmissions and analysis, data warehousing, and processing. SunGuard's co-location services range from high-quality air conditioned space, power, and network access to managed co-location, including security and data backup services. Having superior infrastructure and co-location services combined with Internet support uptime is critical to CardioComm Solutions' business.



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## Marketing Strategy

Following the rapid FDA clearance of the HeartCheck™ PEN, which was roughly 10 months ahead of when the Company had expected, CardioComm Solutions became focused on labeling requirements to sell the product in the U.S., Canada, and Europe, as well as efforts to finalize packaging design, colors, firmware updates, label placements, production logistics, and sourcing of parts. A major challenge faced by CardioComm Solutions in marketing this consumer-based product is that individuals equate conducting an ECG to interacting with a physician and it being conducted in a hospital/medical environment. Thus, the focus of the Company for the HeartCheck™ PEN ECG device is to educate the general public on the two points as identified below.

- (1) The product is a valid, FDA-cleared medical device that allows a patient to do something that was previously impossible—take a reliable ECG from anywhere in the world, manage that recording in a credible manner, and provide an environment where a physician may interact with the recorded ECG to render an interpretation. The device has widespread applicability in the consumer markets, particularly within remote regions of the world or places such as cruise ships, oil rigs, or mines, etc.
- (2) The technology of recording an ECG is not new, and while conventionally an ECG was something associated with a physician's office or medical setting, CardioComm Solutions' technological advances have now made it possible to put the power of ECG recording into the hands of the consumer/patient by leveraging its already available medical software pedigree to enable consumers to benefit from the technologies.

## Distribution Agreements

With a nominal number of HeartCheck™ PENs sold passively through CardioComm Solutions' website at present, the Company is now working with potential distributors that are evaluating the product for use globally, negotiating performance terms, and securing country clearances. There are currently 14 international distributors actively evaluating the HeartCheck™ PEN for use within their territories—where several have accepted applicability of use of the device and have moved to requesting country clearances for the licensed import and sale of these devices and software. In the U.S., two smaller, web-based distributors have been engaged to test the American markets through their respective market niches. The Company intends to formally identify additional distributors as their sales volumes increase and as they demonstrate the capacity to achieve target sales volumes as stipulated in CardioComm's distribution contracts to be executed with them. Some distribution agreements have already been executed with partners; however, performance measures through sales require time. The Company intends to only announce agreements once there is confirmation of hard sales.

As it relates to the Company's HeartCheck™ Handheld ECG device, this product is sold worldwide to hospitals, call centers, and physicians' offices through a combination of an external distribution network and the Company's North American-based sales team. Since January 2013, CardioComm Solutions has received roughly a half dozen requests from U.S.-based companies that are in the traditional medical device arena—with their own sales forces that target physicians, hospitals, and clinics. Internationally, the Company has non-disclosure agreements (NDAs) with a growing list of global distributors in countries such as Indonesia, Malaysia, India, Israel, and the United Arab Emirates (UAE). Based on this interest, the Company has stated that it expects to sign at least two agreements with device companies within the next several months to sell CardioComm Solutions' HeartCheck™ ECG devices into physicians' offices as well as hospitals.

In addition, the following distribution agreements are either in place or in progress:

- *Pharmaceutical Companies.* CardioComm Solutions has stated that it has spoken with two multinational pharmaceutical organizations interested in utilizing an ECG screening technology to detect AF. This is related to new anticoagulation therapies that are recommended for use by individuals after a diagnosis of AF has been made. Appropriate anticoagulation therapy reduces the risk of AF for the purpose of reducing risk of stroke.

- *Pharmacy Chains.* CardioComm Solutions has stated that it is in discussions with several retail pharmacy chains and suppliers regarding providing the HeartCheck™ Handheld ECG monitor for use in pharmacies. Physicians and pharmacies already work together in a referral network. The idea is to leverage this relationship to develop an easy access screening system for patients who are suspected of having arrhythmia-based disorders. Physicians would recommend this screening test based on a patient's symptoms or risk factors. As well, opportunities for a HeartCheck™ PEN sale could follow the monitoring of an individual who has found the screening process to be of value. Purchasing a personal use HeartCheck™ PEN would allow for continued self-monitoring. In addition, pharmacies are interested in adding value to the customer experience and to demonstrate an ability to add to customer health management. Interest has been shown to offer **QT interval** monitoring for individuals, especially where drugs taken may place a person at risk for sudden cardiac death due to prolonged QT. Measure would be performed once per month at the time of prescription refill.
- *Heart Associations.* Working with valued partners, such as the Heart and Stroke Foundation, the World Heart Federation, and the World Hypertension League, and use of the HeartCheck™ devices in clinical research projects, such as within a Canadian Institutes of Health Research (CIHR) grant, could bring increased awareness and acceptance of the Company's HeartCheck™ brand and software monitoring solutions to the consumer and medical markets. CardioComm Solutions is working with AF patient groups to review and endorse the HeartCheck™ PEN to their members. A potentially new market opportunity may come from individuals who are taking medications known to cause cardiac arrhythmias, such as QT interval prolongation, as the HeartCheck™ PEN is an easy and supportive therapy to manage cardiac disease risk.
  - In February 2013 (designated as "Heart Month"), CardioComm Solutions participated in an "American Heart Awareness" campaign through a *USA Today*-based publication, which was released on February 22, 2013. The *USA Today* insert had an estimated reach of roughly 1.5 million readers, and marked 10 years of the American Heart Association's efforts to draw attention to better management and prevention of heart disease and stroke—the number one and two killers identified by the World Health Organization (WHO) in developed and middle-income countries. CardioComm Solutions planned to donate a portion of the proceeds from the sale of the HeartCheck™ PEN from this initiative to the American Heart Association to support Stroke Research ([www.theheartcheck.com/usatoday](http://www.theheartcheck.com/usatoday)).
- *Government Agencies.* CardioComm Solutions is also involved in discussions with The Ontario Ministry of Aboriginal Affairs to be able to deliver the device into aboriginal communities and is working with the Ministry of Community Safety and Correctional Services to deliver the device into correctional facilities.
- *Long-Term Care Facilities.* CardioComm Solutions is currently piloting the use of the HeartCheck™ ECG Monitor for use in residents of long-term care (LTC) facilities responding to claims of palpitations and monitoring for prolonged QT intervals. In addition, use of the Company's 12 lead ECG software solution will be tested since performance of such ECG tests require outside laboratories to visit and service the residents at a premium fee outside that covered by government insurance or the LTC services.
- *Direct-to-Consumer Advertising.* CardioComm Solutions expects to attend a series of Canadian and U.S.-based tradeshows and public events in association with national cardiovascular societies that are also launching initiatives to increase awareness for cardiac health and stroke prevention. These direct-to-consumer campaigns are expected to allow the Company to gauge the direct customer response and interaction with the HeartCheck™ PEN, and lead to a gathering of additional information for use in a go-to-market strategy for big box pharmacy chains that are interested in direct consumer responses to the devices.
  - The first of these events was the Canadian Spring Fishing and Boat show in Toronto. The idea of allowing people to capture arrhythmia recordings at the time they experience them via a HeartCheck™ PEN is highlighted in this consumer demographic.

- **Web-Based Distributors.** The Company currently has two existing web-based distributors as announced in March 2013: (1) firstSTREET for Boomers and Beyond Inc., based out of Virginia; and (2) TAW Global. The firstSTREET for Boomers and Beyond firm specializes in the design and marketing of innovative specialty products for seniors. TAW Global is a marketer of specialty products. Both distributors are selling the HeartCheck™ PEN into the U.S. markets. The HeartCheck™ ECG monitor is available via firstSTREET's catalog and website, as shown in Figure 15. Additional web-based retailers have been contracted though sell on commission without the requirement for pre-purchasing inventory for re-sale. The Company has stated that it intends to announce these other groups as their sales reach a sustainable level.



Source: firstSTREET for Boomers and Beyond Catalog.

### HeartCheck™ PEN Manufacturing

CardioComm Solutions has developed contract partnerships with experts on various components relating to what is needed in order to launch its HeartCheck™ PEN into the market, where ChoiceMMed is to manufacture it. ChoiceMMed (profiled on page 40) is the manufacturer of CardioComm Solutions' diagnostic ECG products—including its handheld ECG monitor as well as its ECG PEN product. The ChoiceMMed facilities are believed to be ISO and FDA compliant. The Company performed two onsite inspections prior to committing to an agreement. ChoiceMMed is capable of manufacturing product within the two plants to meet a production volume of up to 6,000 units per day at full deployment.

The HeartCheck™ devices are formatted with firmware that is customized to CardioComm Solution's proprietary software and patent-pending SMART Monitoring solutions. Labeling of the HeartCheck™ products is in compliance with regulatory agencies in North America (Québec included), South America, and the European Union. Current country clearances secured by the Company in 2012 permit sales to Canada, the U.S., and Europe. With distribution negotiations occurring globally, additional country-specific regulatory approvals are currently underway for Indonesia, Israel, Japan, Kuwait, Malaysia, and Vietnam. Further country clearances could occur for Africa, Costa Rica, Hong Kong, Hungary, Poland, and Taiwan. Packaging currently utilizes a clear hard plastic box that permits the product to be visible as well as labeling and website information. Included in the product is a USB cable, batteries, accompanying user documentation, and warranty information.

### Other Marketed Products

#### GEMSTrak AF™: Cardiac Event Recorder with Atrial Fibrillation Auto-Capture (Prescription Use)

GEMSTrak AF™ is a transtelephonic event loop recorder (ELR), which is utilized to monitor patients while being worn during day-to-day activities for between 14 and 30 days. The ELR offers physicians flexible set-up and configuration and can detect AF with a high degree of accuracy. In addition to symptomatic events recorded by the patient using a manual activation trigger, GEMSTrak AF™ can automatically record asymptomatic ECG arrhythmias without patient involvement. The GEMSTrak AF™ uses embedded algorithms to detect and record episodes of AF, **bradycardia**, and **tachycardia**.

MedNet Healthcare Technologies manufactures GEMSTrak for CardioComm Solutions and the Company is the exclusive distributor of the device in Canada. Transtelephonic ELRs are the current and standard type of ELR used in Canada. While GSM-enabled ELR devices are reimbursed at a higher level in the U.S., this is not the case in Canada and thereby reimbursement levels have been the barrier to entry for non-transtelephonic devices. The GEMSTrak AF™ was introduced when the industry-standard King of Hearts ELR was removed from the market by its manufacturer LifeWatch. LifeWatch has since reintroduced the King of Hearts ELR; however, the distributor price is now significantly higher while the product specifications still reflect those of the original device when it was first released over 10 years ago. CardioComm Solutions plans to offer drivers for the new King of Hearts within 2013 should the market show an interest to purchase the device.

The GEMSTrak AF™ has been configured with a one-hour memory and a pre-programmed allocation of 40 minutes of memory dedicated to manually activated ECG recordings, leaving 20 minutes for automatic detection. Competitive products from LifeWatch and Braemar have 10 and 20 minutes of total memory, respectively, rendering the GEMSTrak device as having the most ECG storage memory of a transtelephonic device.

## Services

### *HeartCheck™ SMART Monitoring*

CardioComm Solutions' patent-pending HeartCheck™ SMART Monitoring service (overviewed in Figure 16) enables individuals to have their heart rhythms viewed, analyzed, and interpreted by a physician, independent diagnostic testing facility (IDTF), ECG Coordinating Center, or both. These technologies are intended to enable, or unlock, personal health monitoring devices that display biosign wave forms and images and can be used for remote access interpretation. The ECG medical call centers employ technicians and physicians who can read and diagnose an ECG within 30 minutes, 24 hours a day, 7 days a week, 365 days a year.

When a patient transmits an ECG, the receiving technician immediately reads the cardiograph and determines what services are necessary—from sending the patient to the hospital, advising the patient to call their physician, or telling the patient that the ECG tracing appears normal. The SMART Monitoring service ensures the interpreted results are returned to the registered consumer in compliance with all privacy and personal information protection regulations and laws. Until now, such devices were available only under physician prescription. Now, with HeartCheck™ SMART Monitoring, along with the Company's HeartCheck™ PEN, CardioComm Solutions can provide a full cycle of market-tested ECG monitoring services to patients.

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Figure 16  
SMART MONITORING SERVICE

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#### **Capture**

Using the HeartCheck™ PEN device, simply take heart readings the moment any symptoms are felt.



#### **Connect**

Using the USB cable provided, connect the device to a PC and run GEMS™ Home to upload patient's heart rhythm files containing the ECGs to a physician or ECG Coordinating Center.



#### **Transmit**

Send heart readings to SMART monitoring or ECG Coordinating Center.



#### **Print or Email**

The ECG Coordinating Center or physician will create an ECG report on a patient's heart analysis identifying any potential issues and the report will be made available on a patient's PC through the GEMS™ Home application.

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*Source: CardioComm Solutions, Inc.*

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### Partnership with SPI Scanning LLC

In May 2013, CardioComm Solutions announced the completion of its infrastructure to ensure a 30-minute ECG interpretation service in support of the HeartCheck™ PEN sales and SMART Monitoring service, forming a partnership with Texas-based SPI Scanning LLC (SPI). SPI is a national healthcare testing corporation established under U.S. federal guidelines as an IDTF and a provider of Holter and event scanning services to hospitals and physicians' offices around the world. SPI is to provide CardioComm Solutions' patients with around-the-clock access to rapid physician ECG interpretations. SPI specializes in overflow scanning to assist busy centers with rapid ECG processing by certified professionals. As volume increases, SPI reading services can be deployed to meet demands. The Company has already developed relationships with ECG reading services in China and the United Kingdom should HeartCheck™ PEN ECG device reading services require expansion overseas. In addition, the Company may leverage its existing relationships with a multitude of additional IDTFs within the U.S. and large core laboratory groups in Canada, should it be required.

Such relationships are significant to CardioComm Solutions as the Company's North American HeartCheck™ PEN users will have access to rapid physician ECG interpretations anytime and anywhere as the Company expands its SMART Monitoring service and infrastructure. The Company believes this is a key form of differentiation between it and other organizations that may be considered competitive threats. CardioComm Solutions' SMART Monitoring service operates in a manner that is similar to large, prescription-only IDTFs in the U.S., seeking to ensure that consumers receive reliable and medically credible results in a timely fashion.

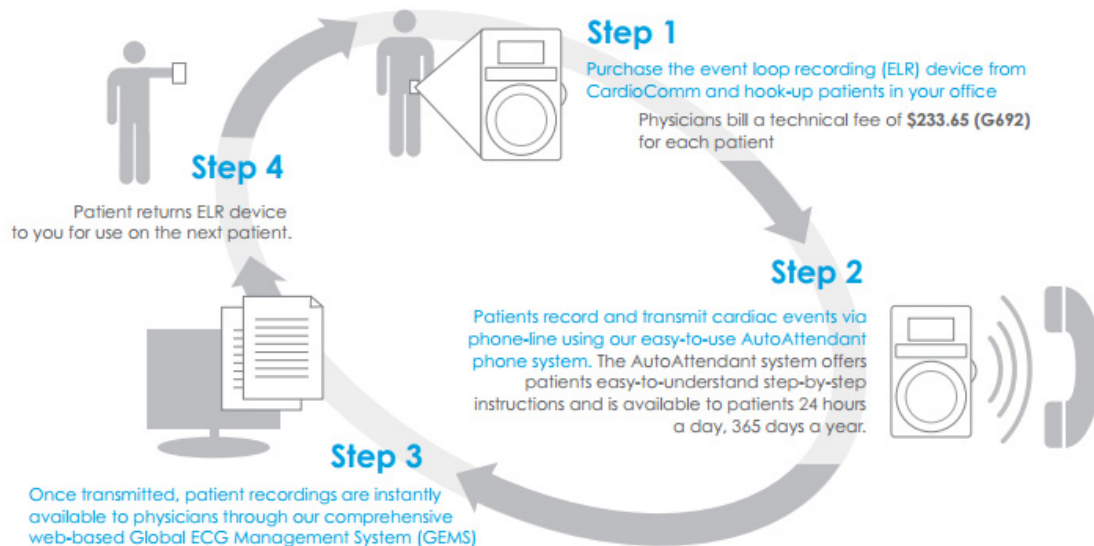
Consumers who purchase CardioComm Solutions' HeartCheck™ PEN ECG will have access to CardioComm Solutions' patent-pending SMART Monitoring service, the free GEMS™ Home software, and one free physician ECG interpretation. After the first free interpretation, the HeartCheck™ PEN and GEMS™ Home PC-based software can be enabled (unlocked) to display the ECG waveform at no additional cost. CardioComm Solutions charges \$12.50 per 30-minute, rapid physician interpretation, regardless of the country and time of origin.

### C4™ ECG Management Service (powered by GlobalCardio™)

As a provider of ECG management services in North America, CardioComm Solutions has made event loop recording (ELR) services available to physicians and clinics to offer through their own offices, such as is shown in Figure 17. C4™ allows for telephonic and wireless-based ECGs to be received in an **application service provider (ASP)** model using a centralized server. These services include data management and interpretation. This product is designed for physicians' offices and enables patient management using a pay-as-you-go business model.

Figure 17

#### CARDIAC EVENT LOOP MONITORING



Source: CardioComm Solutions, Inc.

## Awards

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Figure 18  
FROST & SULLIVAN BEST PRACTICES AWARD

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*Source: CardioComm Solutions, Inc.*

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Based on completing an analysis of CardioComm Solutions' cardiac rhythm monitoring technology industry, Frost & Sullivan recognized the Company with the 2012 North American Frost & Sullivan Award for Enabling Technology (as shown in Figure 18), specifically for leveraging its SMART Monitoring service to launch a fully scalable and cost-effective ECG and arrhythmia monitoring solution. This award comes as the Company has demonstrated industry leadership by introducing its ECG management and monitoring solutions into the consumer market as well as its OTC cardiac rhythm monitoring devices with the option of physician-driven ECG interpretive services. Each year, Frost & Sullivan presents this award to a company that has developed a technology that can benefit or revolutionize the industry. The award recipient has to have developed a system or enabling component of a system that eliminates a substantial hurdle in the development of technology.

Additionally, CardioComm Solutions has received several other key awards related to its technology, as listed below.

- Placed #154 in the 2005 Deloitte Technology Fast 500, which recognizes the 500 fastest-growing technology companies in the U.S. and Canada
- Received the 2004 VIATeC Technology Award for Software of Electronic Service Delivery for Internet-based ECG management software
- Received a 2013 VIATeC nomination for Product of the Year, with CardioComm Solution named as a finalist as of the date this report was prepared



## Competition

The expansion of telemedicine applications, driven largely by technological advancements, has resulted in both established and newer healthcare companies dedicating increasing resources toward this area. Specifically, the cardiac monitoring market has experienced an influx of new devices addressing the need generated by an increased incidence of cardiovascular diseases combined with rising costs of cardiac disease treatment. Although the cardiac monitoring device market is highly competitive, the development of a complete solution incorporating technological advancements, such as wireless technology, enhanced data management systems, and integrated monitoring services, could become a differentiating factor among the variety of options available for professionals and consumers.

The ECG market addressed by CardioComm Solutions is in the billions of dollars. As it relates to the Company's handheld ECG devices, there are other handheld devices on the market; however, to CardioComm Solutions' knowledge, its device is the only device that is FDA cleared for over the counter (OTC) markets and further, it is the only full-service offering incorporating ECG acquisition, physician access for ECG interpretation, and feedback of ECG interpretive reports back to customers in adherence with HIPPA and personal health information privacy regulations within 30 minutes, 24 hours a day, 7 days a week, 365 days a year.

CardioComm Solutions may encounter competition from providers of cardiac monitoring devices, cardiac data management systems, and monitoring services. As it relates to CardioComm Solutions' addressable software market, the Company believes that its patent-pending, patented, and proprietary technologies, which incorporate U.S. FDA-cleared software solutions that are device independent with wireless capabilities and monitoring services, provide a competitive advantage when compared to other solutions in the market. To the Company's knowledge, only two other remote cardiac monitoring software applications have received FDA clearance: Medtronic, Inc.'s (MDT-NYSE) Paceart® and ScottCare Corporation's CardioView Dx™, as profiled in the accompanying section (pages 42 and 43, respectively).

The companies and products listed below are not intended to be an exhaustive collection of CardioComm Solutions' competitors, but rather an indication of the type of competition that the Company may encounter. Importantly, as it relates to certain competitors profiled in the accompanying section, some of these competitors may also currently be or are in the process of becoming collaborators with CardioComm Solutions. Specifically, CardioComm Solutions is currently working with companies, such as Avery Dennison and as Polar Electro, which are each interested in bio-monitoring and, as such, are in collaborative talks with regard to enabling their devices to be used with CardioComm Solutions' software. As well, CardioNet and LifeWatch are U.S.-based companies that provide ECG monitoring services to patients under a physician's prescription (versus as an OTC product) that the Company has approached to expand their capacity and enter into the consumer monitoring market. It is possible that these large IDTFs may seek to work with CardioComm Solutions in the future.

### ***Aerotel Medical Systems Ltd.***

[www.aerotel.com](http://www.aerotel.com)

Aerotel Medical Systems is a closely held provider of mobile and home-based medical diagnostic and monitoring systems and devices for home care, eHealth, and telemedicine markets. The company's patient monitoring systems consist of medical call center software and compact digital monitoring devices designed to transfer essential medical and lifestyle data over the telephone, mobile phone, wireless networks, the Internet, and other electronic media. Aerotel's offerings include the Heartline system, a cardiac diagnostic and monitoring system. Heartline comprises a range of personal portable ECG devices that record and transmit ECG signals to a medical center, where the transmitted data is analyzed and evaluated. CardioComm Solutions software is compatible with several of the Aerotel ECG monitoring devices, which has assisted Aerotel in device sales through several IDTFs in the U.S. Aerotel was founded in 1985 and is based in Holon, Israel, serving customers in India, the U.S., Chile, China, Australia, and Canada.



**AliveCor, Inc.**

[www.alivecor.com](http://www.alivecor.com)

AliveCor is a closely held company headquartered in San Francisco, California, that has developed a clinical-quality, low-cost prescribed mobile ECG device associated with smartphones. Their device enables patients to monitor their heart's health anywhere and at any time via a smartphone only under a physician's prescription, and provides physicians willing to receive their patient's ECGs with an additional assessment tool for their patient's heart health. The company's Heart Monitor for the iPhone® is approved only for use by licensed U.S. medical professionals and may be prescribed to patients in order to record, display, store, and transfer single-channel ECG rhythms. AliveCor does not include access to a medical call center nor any structured system to connect purchasers of their product to physicians.

**Avery Dennison Corporation (AVY-NYSE)**

[www.averydennison.com](http://www.averydennison.com)

Avery Dennison is a California-based Fortune 500® company focused on labeling and packaging materials and solutions. The company operates out of more than 50 countries and employs 30,000 individuals worldwide. Avery Dennison, under the name Vancive Medical Technologies, markets electromedical adhesive products suited to the production of disposable ECG electrodes, grounding plates, and electrode labels. Its medical and healthcare products are skin-friendly adhesives that offer high and sustained adhesion with no residue after removal. Avery Dennison has commenced operations of a new medical division, called Vancive, which is developing a patch-based ECG monitoring technology. CardioComm Solutions is in discussions with Avery where CardioComm Solutions is to have its software integrated with Avery's new device.

**Beijing Choice Electronic Tech Co., Ltd**

[www.choicemmed.com](http://www.choicemmed.com)

Beijing Choice Electronic (ChoiceMMed) was founded in August 1993 and has grown into a major enterprise in the global healthcare industry. The company develops innovative health products for global medical institutions and family support. In 2006, the company launched the first home-use, handheld ECG monitor and wrist BP/SpO<sub>2</sub> monitor and in 2011, introduced telemedicine products, including the Tele-ECG Monitor and Tele Multi-Parameter monitor products. ChoiceMMed is the manufacturer of CardioComm Solutions' diagnostic ECG products, including its handheld ECG monitor as well as its ECG PEN product. As well, the company is bringing to market other devices for which CardioComm Solutions will likely have the right of first refusal to integrate. Headquartered in Beijing, ChoiceMMed has 8,000 square meters of international standard industrial workshops, fitted with precision research equipment and inspection equipment, according to ISO 13485 and QSR 820 quality specifications. ChoiceMMed has an extensive mobile sales force, with CardioComm Solutions in discussions to leverage that sales force to sell the HeartCheck™-brand products, thus making ChoiceMMed a distributor to CardioComm Solutions as well. ChoiceMMed, with headquarters in Beijing, China, has customers in 89 countries and regions, and its products have entered into global professional medical institutions.

**Cardiac Designs**

<http://cardiacdesigns.com>

Cardiac Designs of Park City, Utah, has the only FDA-cleared OTC iPhone® Heart Monitor, launched in May 2013. This user-friendly ECG Check recorder turns the iPhone 4S or iPhone 5 into a heart monitor with automated analysis and reporting. Similar to AliveCore's Heart Monitor, which is cleared for prescription use, the ECG Check leverages the power and interactivity capabilities of the iPhone 4S/5 to accurately and quickly record, analyze, report, and store an individual's heart rhythms. The device was submitted to the FDA on July 23, 2012, one week before AliveCor's July 30, 2012, submission. While the device is approved for OTC sales, it is not approved to display ECG wave forms and does not have an ECG call service associated with its offerings.

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**CardioNet, Inc. (BEAT-NASDAQ)**

[www.cardionet.com](http://www.cardionet.com)

CardioNet is a provider of real-time ambulatory outpatient management solutions for monitoring a patient's clinical information. The company's efforts are focused on the diagnosis and monitoring of cardiac arrhythmias through its two business segments: patient services and products. The patient service business segment offers Mobile Cardiac Outpatient Telemetry™ (MCOT)—an integrated patient management platform that incorporates a wireless data transmission network, internally developed software, medical devices, and digital monitoring services. The product business segment focuses on the development, manufacturing, testing, and marketing of medical devices and related software to medical companies, clinics, and hospitals. The company is headquartered in Conshohocken, Pennsylvania, and was founded in 1999. CardioNet acquired Braemar and as a result CardioComm Solutions' GEMS™ software is now compatible with both transtelephonic and well as GSM-enabled ELR devices manufactured by CardioNet.

**Clearbridge Vitalsigns Pte Ltd.**

[www.clearbridgevitalsigns.com](http://www.clearbridgevitalsigns.com)

Clearbridge Vitalsigns is a National University of Singapore (NUS) spin-off company developing the CardioLeaf® product line—a fully integrated, ultra-thin, ultra-low power, multi-lead (up to 12-lead), extended wear medical device to monitor human vital signs. The company aims to commercialize its wearable, discreet, and ultra-sensitive vital signs monitoring devices for use in ambulatory, in-patient care, and for professional fitness. Clearbridge has headquarters in Singapore.

**Corventis, Inc.**

[www.corventis.com](http://www.corventis.com)

Corventis designs and develops wireless cardiovascular equipment. The company's product offerings include the NUVANT Mobile Cardiac Telemetry (MCT) system, which provides continuous surveillance of symptomatic and asymptomatic cardiac abnormalities; and the AVIVO mobile patient management system, which offers continuous monitoring of key vital signs to assist physicians in tracking patients' health status and detecting potential health risks. The company was founded in 1995 and is based in San Jose, California.

**eCardio Diagnostics, LLC**

[www.ecardio.com](http://www.ecardio.com)

eCardio is a provider of comprehensive technologies, devices, services, and solutions for the diagnosis, monitoring, and clinical management of cardiac arrhythmias, predominantly in an ambulatory setting. The company offers an array of clinical services and cardiac monitors designed to streamline and improve the process of remote arrhythmia monitoring, optimize patient care, increase patient compliance, and decrease the time required to diagnose an arrhythmia. eCardio was founded in 2004 and is headquartered in Houston, Texas.

**iRhythm Technologies, Inc.**

[www.irhythmtech.com](http://www.irhythmtech.com)

iRhythm is focused on ensuring that cardiac rhythm monitoring becomes more accessible and available to patients at risk for an arrhythmia. The company markets its products under the Zio® platform. For physicians, the Zio® aids in patient diagnosis by combining a simple, sophisticated device with a clear report format. For clinical staff, this is a hygienic, new device for each patient, and a service team providing 24/7 support to help clinical staff members care for their patients. For patients, the devices offer an inconspicuous, easy-to-wear monitor that is designed to enhance compliance and simplify the monitoring experience, while maximizing diagnostic yields. iRhythm is a customer of CardioComm Solutions and is one of the largest GEMS™ license holders in the market space. The company has headquarters in San Francisco, California, and CardioComm Solutions' software is utilized to operate the Zio® patch.

**LifeWatch Corp. (A subsidiary of LifeWatch AG [LIFE-SIX])**

[www.lifewatch.com](http://www.lifewatch.com)

LifeWatch is a healthcare technology and solutions company providing remote patient monitoring services and developing, manufacturing, and marketing telehealth systems. Through its subsidiary, LifeWatch Services Inc., the company offers cardiac monitoring services and products, including the following: (1) LifeStar™ ACT ambulatory cardiac telemetry system, which allows for the capture, transmission, and analysis of irregular ECG data without the need for patient intervention; (2) LifeStar PMP, a wireless telediagnostic system for patients suffering from congestive heart failure, diabetes, and **chronic obstructive pulmonary disease (COPD)**; (3) LifeWatch Connect EMR Platform, a web-based clinical management solution; and (4) NiteWatch home sleep testing, a service for unattended sleep monitoring of patients with obstructive sleep apnea. LifeWatch is a U.S.-based subsidiary of LifeWatch AG, a healthcare company headquartered in Neuhausen and Rheinfall, Switzerland, with additional subsidiaries in the Netherlands, Japan, the UK, and Israel.

**MD Biomedical Inc.**

<http://en.iwebecg.com>

MD Biomedical of San Juan Capistrano, California, markets the slim and lightweight Vion Portable Hand-held ECG Monitor. This device is designed for at home use and is able to check a person's heart condition anytime and anywhere. With one press and a 30-second record, individuals can get a snapshot of their heart and have the full records stored on the computer or online, to be reviewed individually or by healthcare professionals.

**MedNet Healthcare Technologies, Inc.**

[www.mednethealth.net](http://www.mednethealth.net)

MedNet provides a remote cardiac monitoring solution that features both patient monitoring services and medical device manufacturing. MedNet's Heart-Care monitoring centers integrate a spectrum of monitoring technologies and patient management systems to offer optimum support to clinicians and cardiac patients. The company's Universal Medical division engineers and manufactures ambulatory cardiac monitors and supporting systems. While the division is vertically integrated with MedNet's monitoring division, Universal Medical also markets its product line directly to physicians' offices, hospitals, and IDTFs. MedNet manufactures a private-label version of its ELR for CardioComm Solutions under the GEMS™Trak brand. The company was founded in 1989 and is headquartered in Ewing, New Jersey. CardioComm Solutions had been in discussion with MedNet for potential integration of MedNet's ECG monitoring devices with the suite of CardioComm Solutions' technologies, as was accomplished with the GEMSTrak AF™ transtelephonic ELR.

**Medtronic, Inc.**

[www.medtronic.com](http://www.medtronic.com)

The Medtronic Paceart® system is a computer software application that allows clinics to manage follow-up of implantable cardiac device patients by collecting and organizing relevant patient, cardiac device, and programmer information. The system serves as a gateway for the transmission of data—from remote cardiac monitoring devices to a clinic's electronic health record (EHR) system. The Paceart® system collects and organizes the data, acting as a central repository for a patient's arrhythmia information. The system works with devices from different manufacturers. Paceart® is used by participants in the ECG monitoring market in the U.S. Medtronic acquired the Paceart® business from General Electric's Medical Systems unit in 2002. Medtronic has taken the Paceart® module and accommodated a new type of device that transfers the ECG wirelessly—that is the Mobile Cardiac Telemetry (MCT) device. Medtronic manufactures and sells device-based medical therapies worldwide. The company's offerings include cardiovascular products to diagnose, treat, and manage heart rhythm disorders and heart failure. Medtronic was founded in 1949 and is headquartered in Minneapolis, Minnesota.

The Paceart® source code is licensed to clients who may then modify the software to accommodate their specific workflow requirements. Paceart® is not FDA cleared for use with wireless devices though several IDTFs do use this software for GSM-based **current procedural terminology (CPT)** code billings. The Paceart® software's 510(k) clearance does not extend to wireless or 12 lead devices.

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**OMRON Healthcare, Inc. (part of OMRON Global)**

[www.omronhealthcare.com](http://www.omronhealthcare.com)

Omron Healthcare is a leading manufacturer and distributor of wellness products. The company's products include home blood pressure monitors, fitness tools (e.g., pedometers and heart rate monitors), and electrotherapy devices. Omron was the first company to introduce manual and digital blood pressure monitors into the home healthcare market, where the company's monitors provide consistently accurate blood pressure readings. The company also markets a portable prescribed ECG monitor among its other products. OMRON Healthcare has headquarters in Lake Forest, Illinois.

**Polar Electro Inc.**

[www.polarusa.com](http://www.polarusa.com)

Polar Electro of Lake Success, New York, has been committed to conducting innovative physiological and sports medical research since the 1980s and now offers some of the most advanced heart-rate based training equipment in the world. All of the features in the company's products are based upon scientific work and are in accordance with recommendations from global sports medicine authorities. Beyond individuals who are interested in their personal well-being, Polar's heart rate monitoring and analyzing technology has been used by numerous researchers in the fields of sports, exercise, and health. The company's product selection includes heart rate monitors for running, fitness, and cross-training, as well as GPS-enabled cycling computers and sports watches for endurance training. CardioComm Solutions has stated that it is in discussion with Polar Electro Oy to be able to integrate the hardware being developing with CardioComm Solutions' software and provide a credible method to monitor consumers who are interested in looking at arrhythmias and heart rates.

**REKA Health Pte Ltd.**

[www.rekahealth.com](http://www.rekahealth.com)

REKA Health markets the E100, which is a single lead cardiac event monitor designed for home and self-care purposes. The device offers high consumer usability while fulfilling all necessary medical regulatory requirements, including FDA and CE certifications. The E100 is intended for screening patients who present with transient cardiac symptoms for early-stage arrhythmia only under physician prescription. This pocket-sized system is intended to provide patients with full portability and the convenience of recording their own ECG anytime and anywhere. Patients are able to proactively administer self-care measures if and when necessary, while maintaining their personal health data accurately and efficiently. The E100 has a user-friendly interface and is able to capture error-resistant single lead ECG readings with minimal effort on the part of the user. The device can be used to instantly obtain an accurate 30-second ECG record, which is then uploaded to REKA Health's cloud platform through its proprietary PC or mobile applications. The patient's physician or cardiologist can review the record and offer feedback instantly, thus facilitating communication and extending the patient/physician relationship beyond the clinical setting. The company is based in Singapore, with U.S. offices in San Diego, California.

**ScottCare Corporation (a Scott Fetzer Company)**

[www.scottcare.com](http://www.scottcare.com)

ScottCare provides medical systems and software solutions for cardiovascular diagnostic monitoring and cardiac rhythm device management. The company operates as a cardiology device reseller with their main ECG-based offering being its CardioView Dx™ Suite, a single-platform solution for cardiovascular diagnostic monitoring and cardiac rhythm device management. CardioView Dx™ includes TeleSentry™, an MCTsolution; OneView™ CRM, a pacemaker or **implantable cardioverter defibrillator (ICD)** monitoring solution; Chroma™, a Holter monitoring solution; as well as arrhythmia/event and blood pressure monitoring systems. ScottCare also provides TeleRehab VersaCare, a telemetry solution for cardiopulmonary rehabilitation; and ViaCare ECP, a therapy system for the treatment of angina and congestive heart failures. In addition, the company offers components and ECG software development services to companies in the medical device and arrhythmia monitoring service fields. Founded in 1989 and based in Cleveland, Ohio, ScottCare operates as a subsidiary of The Scott Fetzer Company, part of a diversified group headquartered in Westlake, Ohio, and wholly owned by Berkshire Hathaway Inc. (BRK-A; BRK-B-NYSE).

***SHL Telemedicine Ltd. (SHLTN-SIX)***

[www.shl-telemedicine.com](http://www.shl-telemedicine.com)

SHL Telemedicine Ltd. is a provider of remote health services in cardiology and in other medical areas. The company specializes in developing and marketing advanced personal telemedicine systems and solutions, including medical call centers and monitoring centers. SHL Telemedicine provides portable monitoring devices that allow individuals to transmit medical data via phone lines to call centers where the data can be processed and analyzed by medical personnel. SHL's rhythm and monitoring services employ CardioComm Solutions' ECG viewer software, which is licensed on an annual basis. Founded in 1987, SHL is headquartered in Tel Aviv, Israel. In the U.S., certain SHL telemedicine products are distributed by Philips Healthcare.

## Key Points

- CardioComm Solutions is an innovator of solutions for information management in cardiovascular medicine and telemedicine. The Company's integrated electrocardiogram (ECG) and arrhythmia monitoring products and services enable patients, medical professionals, and healthcare experts to quickly and easily access and manage patient information in a secure, reliable environment from anywhere in the world.
- CardioComm Solutions' primary ECG solutions include medical monitoring software technologies—GEMS™ (Global ECG Management Systems), GEMS™ Home, and GlobalCardio™—as well as the HeartCheck™ brand of ECG devices—the HeartCheck™ ECG Handheld (used in a medical setting) and the newly launched HeartCheck™ PEN device (the first FDA-cleared, handheld over-the-counter [OTC], consumer-targeted product). These devices are supported by software programs and SMART Monitoring services, which CardioComm Solutions has developed to enable 24/7 patient monitoring and objective diagnoses, with integration into existing electronic medical records (EMRs), among many other features.
- **Software.** The Company's software products for the diagnosis of ECG abnormalities, marketed as GEMS™ and GlobalCardio™, have been used worldwide for several years in hospitals, call centers, and physicians' offices under prescription. CardioComm Solutions' GEMS™ Home is a consumer heart rhythm management solution based on the proprietary GEMS™ and GlobalCardio™ software.
  - CardioComm Solutions is currently rewriting software code, ultimately seeking to convert its software to be compatible with multiple bioscience/biometric monitoring devices, perhaps able to expand monitoring up to 10 channels—such as glucometers, spirometers, weight scales, thermometers, etc.—used in either an OTC or prescriptive fashion with its SMART Monitoring service technologies.
- **Hardware.** The Company's personal handheld ECG device, the HeartCheck™ PEN, is a consumer-based product that allows patients to be monitored at home—enabling the ability to receive proper cardiac care as soon as symptoms are realized. This is believed to represent the only FDA-cleared OTC device in North America able to offer personal ECG monitoring.
  - CardioComm Solutions is focused on educating individuals of the need for cardiac monitoring as the industry transitions to monitoring in the home environment. Much like how individuals were educated 30 to 40 years ago regarding the use of home blood pressure tests, glucometers, and pregnancy tests, etc., which are now standard monitoring devices, and more recently with newer HIV tests, glucose monitors, and more, such testing has moved into the home environment and is now widely accepted.
- **Services.** CardioComm Solutions' HeartCheck™ SMART Monitoring services support the HeartCheck™ PEN and enables patients to have heart rhythms analyzed, interpreted, and diagnosed by a physician, ECG Coordinating Center, or both within 30 minutes, 24 hours a day, year round.
- The Company has a relationship with SunGard as a co-location facility for the housing of the SMART Monitoring services. SunGard is an organization with more than 17,000 employees worldwide and serves approximately 25,000 customers in more than 70 countries. The SunGard ECS is an Infrastructure-as-a-Service offering that allows CardioComm Solutions to view, manage, and request computer resources on demand, while delivering higher efficiency and availability for customer production applications, multi-site recovery options and 99.95% infrastructure uptime. By leveraging the Company's software solution capabilities with SunGard, CardioComm Solutions believes it can reduce the cycle time to ramp up and execute an aggressive go-to-market strategy within another country rapidly and cost effectively since SunGard's Enterprise Cloud Services can meet CardioComm Solution's critical requirements for reliable infrastructure, while ensuring the scalability to handle the significant software growth expected.

- CardioComm Solutions currently has clients in over 20 countries, leveraging its existing hospital and call center-based relationships. The Company's products are cleared for sale globally and CardioComm Solutions holds the required clearances in order to sell software and hardware related to this field. Furthermore, CardioComm Solutions sells software as a license, with individuals accessing the software as a paid for use. CardioComm Solutions currently has multiple-year licenses with Philips Healthcare, which uses CardioComm Solutions' ECG viewer. In addition, GE Healthcare sells a private-label version of CardioComm Solutions' GEMS™ software.
- The Company entered into an agreement with Sensor Mobility, Inc. to develop and enable wearable ECG monitoring devices with Global System for Mobile (GSM) communications transmitting technology. In conjunction, CardioComm Solutions announced a \$4 million pre-placement financing and joint venture agreement ahead of an initial public offering (IPO) of a newly formed U.S.-based subsidiary, called iMedical.
- In May 2013, the Company announced that it had filed for U.S. and Canadian patents to use its proprietary technologies in the automated, software-enabled server-based unlocking of OTC, consumer-based, bio-monitoring devices, permitting CardioComm Solutions to apply the statement "Patent Pending SMART Monitoring service" in its corporate materials until the application process has been completed.
- CardioComm Solutions participates in the remote patient monitoring market—a market with significant growth potential. Healthcare market research firm Kalorama Information predicts that the remote and wireless patient monitoring market could grow from \$6 billion in 2011 to more than \$18 billion by 2014, with an annualized growth of more than 25%.
- In January 2013, CardioComm Solutions received a \$1 million line of credit from MD Primer Inc., which the Company may use on an as-needed basis. Secured against CardioComm Solutions' assets, any amounts drawn by CardioComm Solutions on the line of credit will bear simple interest at prime plus 2.5% per year, where interest is payable monthly. Any principal owing on the line of credit will be repayable on or before December 31, 2015. As of March 31, 2013, the Company's cash position was roughly \$54,000.



## Historical Financial Results

Figures 19, 20, and 21 (pages 47-49) provide a summary of CardioComm Solutions' key historical financial statements: its consolidated Statements of Loss and Comprehensive Loss, Statements of Financial Position, and Statements of Cash Flows as of March 31, 2013. The year 2012 represented one of the Company's largest losses in its history, though it was the only year that CardioComm Solutions did not go into debt. As well, accounting rules dictated that an amount of roughly \$600,000 became a loss due to management stock options being granted (versus an actual cash loss).

Figure 19  
CardioComm Solutions, Inc.

CONSOLIDATED STATEMENTS OF LOSS, COMPREHENSIVE LOSS, AND DEFICIT  
(Expressed in Canadian Dollars) (Unaudited – Prepared by Management)

For the three months ended March 31,	2013	2012
Sales	\$ 612,723	\$ 694,879
Operating expenses:		
Operations	470,213	247,464
Sales, service, and support	185,807	294,177
Marketing	4,642	37,511
Research and development	209,824	276,375
	870,486	855,527
Loss before the following	(257,763)	(160,648)
Foreign currency translation gain (loss)	7,580	(8,547)
Interest	—	151
Other	—	—
Loss and comprehensive loss for the period	(250,183)	(169,044)
Basic and diluted loss per share	\$ (0.00)	\$ (0.00)
Weighted average number of shares outstanding	99,387,667	83,930,765

Source: CardioComm Solutions, Inc.

Figure 20  
CardioComm Solutions, Inc.  
CONSOLIDATED BALANCE SHEETS

(Expressed in Canadian Dollars) (Unaudited – prepared by Management)

	March 31, 2013	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 53,965	\$ 99,867
Accounts receivable	495,043	226,238
Inventory	559,275	579,793
Prepaid expenses and deposits	127,246	36,506
	1,235,529	942,404
Equipment (note 3)*	62,160	66,890
Intangible assets (note 4)	12,884	12,232
	\$ 1,310,573	\$ 1,021,526
<b>Liabilities and Shareholders' Equity (Deficiency)</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 361,668	\$ 266,136
Due to related party (note 5)	89,576	17,030
Current portion of obligation under financial lease (note 9)	18,012	17,905
Deferred revenue	199,985	171,157
	669,241	472,228
Long-term liabilities:		
Obligation under finance lease (note 9)	21,563	26,107
	690,804	498,335
Shareholders' equity (deficiency):		
Share capital (note 7)	27,689,267	27,456,317
Contributed surplus (note 7)	2,620,990	2,438,649
Other paid-in capital (note 7)	768,187	836,717
Deficit	(30,458,675)	(30,208,492)
	619,769	532,191
Continuing operations (note 1)		
Commitments and contingencies (note 9)		
Subsequent events (note 14)		
	\$ 1,310,573	\$ 1,021,526

\*See accompanying notes to consolidated financial statements, as presented in CardioComm's Interim Financial Statements filed with [www.sedar.com](http://www.sedar.com) on May 30, 2013.

Source: CardioComm Solutions, Inc.

Figure 21  
CardioComm Solutions, Inc.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(Expressed in Canadian Dollars)

For the three months ended March 31,	2013	2012
Cash provided by (used for):		
Operations:		
Loss for the year	\$ (250,183)	\$ (169,044)
Items which do not involve cash:		
Amortization of property and equipment	11,906	7,934
Stock-based compensation expense	154,761	65,296
Fees paid in shares	15,000	—
Changes in non-cash working capital balances (note 8)*	(214,667)	(1,094,854)
	(283,183)	(1,190,668)
Financing:		
Issuance of common shares and warrants for cash	177,000	2,661,006
Subscription receivable	—	(70,000)
Advance from (repayment to) related party	72,545	(388,662)
Repayment of obligation under finance lease	(4,436)	—
	245,109	2,202,344
Investing:		
Purchase of property and equipment	(7,828)	(8,657)
Increase (decrease) in cash	(45,902)	1,003,019
Cash, beginning of period	99,867	391,522
Cash and cash equivalents, end of period	\$ 53,965	\$ 1,394,541
Supplemental cash flow information:		
Interest paid	\$ 895	\$ 777
Supplemental disclosure of non-cash transactions:		
Settlement of debt for shares	—	—
Gain on share settlement of related party transactions	—	—

\*See accompanying notes to consolidated financial statements, as presented in CardioComm's Interim Financial Statements filed with [www.sedar.com](http://www.sedar.com) on May 30, 2013.

Source: CardioComm Solutions, Inc.

## Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared for CardioComm Solutions, Inc. (“CardioComm Solutions” 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 CardioComm Solutions’ public documents as well as other forms filed from time to time.

The content of this report with respect to CardioComm Solutions has been compiled primarily from information available to the public released by the Company through news releases, its website, and corporate presentations. CardioComm Solutions 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 CardioComm Solutions 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 twelve thousand U.S. dollars and equity of four hundred fifty thousand shares of CardioComm Solutions, Inc. for its services in creating this report, for updates, and for printing costs. Investors should carefully consider the risks and information about CardioComm Solutions’ business described below. Investors should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties overviewed in CardioComm Solutions’ materials may not be the only risks that the Company faces. Additional risks and uncertainties not presently known to CardioComm Solutions 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, CardioComm Solutions’ business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information 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. For more complete information relating to the risks involved in an investment in CardioComm Solutions, as well as to receive additional information about the Company, its public filings, or to receive copies of this Executive Informational Overview®, either in paper or electronic format, please contact CardioComm Solutions at (416) 977-9425.

### Going Concern

CardioComm Solutions’ consolidated financial statements (pages 47-49) have been prepared on the going concern basis, which assumes the Company will continue in operation for the foreseeable future and be able to realize its assets and discharge its liabilities in the normal course of business. There is uncertainty about the appropriateness of the use of the going concern assumption because the Company has incurred significant losses and negative cash flows from operations since inception, including a loss of \$3,342,457 for the year ended December 31, 2012, and a cumulative deficit of \$30,208,492 as at December 31, 2012, which have been financed with equity. The application of the going concern assertion is dependent on the Company’s ability to generate positive cash flow from operations and/or to obtain additional financing. The Company’s consolidated financial statements do not reflect adjustments that would be necessary if the going concern assumption were not appropriate. If the going concern basis was not appropriate for these financial statements, then adjustments would be necessary to the carrying value of assets, the reported expenses, and the balance sheet classifications used.

There can be no assurance that CardioComm Solutions’ planned product and operational developments will occur as planned. CardioComm Solutions is undercapitalized, which may prevent the Company from moving quickly to continuously upgrade its software and execute on its anticipated product roadmap—activities that CardioComm Solutions believes are necessary to stay abreast of its competition. It may also dampen the Company’s ability to execute on its sales and marketing efforts at the scale that CardioComm Solutions would like and in a manner that is necessary to keep ahead of the market and competition. No assurance can be given that the Company will succeed in the development or commercialization of future products, software, or technologies.

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## **Competition**

The medical device and software industries are each subject to intense competition and rapid and significant technological change. CardioComm Solutions' potential competitors may have significantly greater financial and technical resources than CardioComm Solutions, and superior experience and expertise. Pages 39-44 profile a selection of some of CardioComm Solutions' potential competition, noting that this is not an exhaustive collection of competitors but is merely intended to provide a representation of the type of competition the Company may encounter as it seeks to introduce new products and technologies and increase its presence in its markets. New companies, institutions, or competitive programs known or unknown to CardioComm Solutions may also arise that could alter the outlook for CardioComm Solutions' products or technologies. Of the known companies listed, CardioComm Solutions either has an ongoing relationship with them or has developed capacities such that there is minimal competitive threat. To CardioComm Solutions' knowledge, no company with approvals to sell products in North America is in a position to sell an ECG viewing device at the consumer level. And in this regard, the Company has filed two patent applications to protect this position.

## **Intellectual Property**

CardioComm Solutions relies on a combination of patents, patent-pending, trade secrets, trademarks, and copyrights to protect its intellectual property rights. If CardioComm Solutions is unable to adequately protect its proprietary rights or becomes subject to a claim of infringement, its business may be materially adversely affected. Moreover, if any of CardioComm Solutions' products or technologies are found to infringe on the intellectual property rights of a third-party, the Company may be forced to defend itself, which could divert management's time and resources away from business development, alter or cease development or marketing of its products or technologies, pay license fees to a third party, or suffer other impacts not presently known. Going forward, CardioComm Solutions cannot be certain that patents will be issued with respect to any of its pending or future patent applications. In addition, the Company does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that these patents will prevent the development of competitive patents.

## **Market Risks**

The market for remote cardiac monitoring is emerging. CardioComm Solutions' success will depend, in part, on the degree to which its technology is accepted by medical professionals, patients, clinics, hospitals, third-party payers and now consumers. Presently, it is difficult to assess or predict with any assurance the potential size, timing, and viability of market opportunities for the Company's technology in this market. Additionally, changes in the general domestic and international economic climate may adversely affect the performance of the Company and the level of market demand for its products. As well, healthcare and technology markets are characterized by a continual search for technological advancements that deliver improved reliability and performance at a reduced cost. The Company's growth and future financial performance will depend on its ability to enhance its existing technology and develop and introduce new products on a timely basis to keep pace with technological developments and evolving industry requirements. If CardioComm Solutions is unable to do so, there may be a material adverse effect on its business. If CardioComm Solutions fails to anticipate or respond adequately to changing technological, market, or customer needs, or if it experiences any significant delays in product development, the Company's products may become obsolete and it may not be able to sustain or grow its business.

The Company is targeting the over 40 years old demographic for the purchase of its consumer products and specifically those with hypertension and/or diabetes. The Company's efforts to support GSM-enabled wearable technologies for ambulatory monitoring of cardiac patients will assist in maintaining the Company's preferred provider status in the IDTF markets as well as to position it as a new entrant to the global medical monitoring markets. As new device technologies are released, the Company plans to develop a device integration process to enable access to such products to the North American markets under the Company's current regulatory approvals and patent-pending proprietary intellectual property. This could offer new technologies and faster and cost-effective entry options to new markets.

## **Regulatory Approvals**

The business of manufacturing and distributing medical devices is increasingly exposed to significant legislative compliance issues and regulatory requirements, such as regulation by Health Canada and the FDA as well as under a Medical Device Directive (CE Mark) in the EU. In 2012, CardioComm Solutions achieved five different device clearances for its HeartCheck™ PEN, including two U.S. FDA clearances. The first clearance was for the HeartCheck™ PEN to be sold by the Company as an over-the-counter (OTC) product, for which it was cleared by the FDA in only five days. The second clearance was as a prescription product. CardioComm Solutions also received two similar clearances from Health Canada in September 2012 and a CE Mark in November 2012 (indicating compliance with EU legislation and enabling the free movement within the European market).

Despite the Company's demonstrated ability to secure device and software regulatory clearances and approvals, there is no guarantee that CardioComm Solutions' new products will obtain similar regulatory approvals across the U.S., Canada, and other countries where CardioComm Solutions' products may in the future be used. Even if such approvals are granted, there is no guarantee as to the time taken or cost involved. Sales of products in multiple jurisdictions are subject to diverse foreign regulatory requirements that vary from country to country. Such laws and regulations regarding the manufacture and sale of CardioComm Solutions' products are also subject to future changes, as are administrative interpretations and policies of regulatory agencies. If the Company fails to comply with applicable laws or regulations, it could be subject to enforcement actions—product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties—that may materially harm its business. In an effort to mitigate such risks, the Company utilizes in-country representatives who will be responsible for securing such approvals for the CardioComm Solutions products to be imported, distributed, and sold. It is especially true for regions outside of North America and the European Union, since the Company's products have been cleared within these jurisdictions for the past 15 years. In-country representatives are also asked to assume the costs for securing and maintaining such fees.

## **Ability to Manage Growth**

CardioComm Solutions is subject to all of the usual risks typical of early-stage organizations, including capital adequacy, cash flow, product development and regulatory approval, market penetration and market growth, and continuity of core personnel. Notwithstanding, the Company anticipates growth over the next few years as it strengthens its existing software and launches new products and technologies. CardioComm Solutions' strategy for such growth and anticipated milestones is described on pages 10-14. Growth may place strain on management, and there can be no assurance that CardioComm Solutions will be able to effectively manage this growth in the future without increased sales revenue. The Company has utilized equity-based financing to meet cash flow requirement and has operated for the past two years with no long term debt (other than leases) and only operational debt. In addition, contracts that require capital or human resource commitments involve start-up payments/deposits, milestone-based fees and completion fees, thereby promoting some degree of cash smoothing month to month.

Additional factors that may materially harm or make difficult the Company's timing and pace of growth include the following:

- Manufacturing delays, disagreements, changes in suppliers or terms of supply agreements, poor quality control, or other problems relating to CardioComm Solutions or manufacturers of the Company's products;
- Product liability claims arising from the manufacturing, marketing, sale, and use of CardioComm Solutions' medical devices, which could damage the Company's reputation and financial results;
- An inability of CardioComm Solutions to establish and/or maintain effective sales channels for its products, or a failure on behalf of the Company's distributors and partners to market and sell products;
- Changes in legislation or government policy regarding healthcare laws or medical device requirements, costs, and insurance coverage and reimbursements; and
- The occurrence of a catastrophic disaster, cyber-attack, or other similar event that could damage the Company's facilities and equipment, which could require cessation or curtailing of operations.

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## Dependency on Management and Other Key Personnel

The Company depends on its senior executive officers as well as key personnel. The loss of any of these individuals could harm its business and significantly delay or prevent the achievement of business objectives. Competition for qualified employees is intense among medical device and software companies, and the loss of qualified employees, or an inability to attract, retain, and motivate additional highly skilled employees, could hinder CardioComm Solutions' business.

## Financial Risk Management and Financial Instruments

The Company is exposed to credit risk, liquidity risk, and market risk. Its primary risk management objective is to protect income, cash flows, and shareholder value. Risk management strategies are designed and implemented to ensure that the risks and the related exposures are consistent with CardioComm Solutions' business objectives and risk tolerance. The Board of Directors has primarily been accountable for the establishment and oversight of the Company's financial risk management framework and the Board of Directors delegates senior management with the responsibility for appropriate execution of related strategies. Within the Company's risk management framework, senior management evaluates a variety of alternatives and financial products to augment the risk management process. The Board of Directors reviews and approves all material transactions.

The Company's risk management and treasury policies are intended to: establish acceptable risk boundaries; analyze and identify the risks and opportunities encountered by the Company; monitor and manage the risk exposures due to market changes; and maintain adherence to controls. These policies are reviewed periodically and adjusted accordingly based on the Company's activities and market conditions. The Company's risk management framework is monitored by its Audit Committee, which oversees the appropriateness and adequacy of the risk management framework as it relates to the risks faced by CardioComm Solutions.

### *Credit Risk*

Credit risk is a risk of financial loss arising from an unfulfilled contractual obligation due to the Company by a customer or counterparty to a financial instrument. The carrying amount of financial assets represents the maximum credit exposure. The Company's exposure to credit risk is subject to the concentration of its key customers. The Company's three largest receivable balances due from its customers represent 72% of consolidated accounts receivable at December 31, 2012 (2011–62%). These three customers have been transacting with the Company for many years without any significant occurrence of losses to the Company.

CardioComm Solutions records an allowance for doubtful accounts related to accounts receivable that are considered to be non-collectible. The allowance is based on the Company's knowledge of the financial condition of its customers, the aging of the receivables, current business environment, customer and industry concentrations, and historical experience. To reduce credit risk, cash equivalents are only held at major financial institutions and management provides ongoing credit evaluations of its customers' financial condition.

Total accounts receivable as at December 31, 2012, amounted to \$226,238 (2011–\$292,878), which management believes adequately reflects the Company's credit risk. Of the reported accounts receivable, 16% is determined to be past due, which is defined as amounts outstanding beyond normal credit terms and conditions for the respective customers. The Company does not believe that it is exposed to an unusual level of credit risk.

### *Liquidity Risk*

Liquidity risk is the risk that the Company will be unable to meet its financial obligations as they come due. The Company manages its liquidity risk by managing its capital structure, including forecasting cash flows. These are complemented with regular reviews of operations, business conditions, and seasonality to ensure that adequate future liquidity needs are met with a level of certainty, and within acceptable risk exposure. The Company's objective is to ensure that it has sufficient available cash on hand to meet normalized operating expenses. CardioComm Solutions' ability to manage liquidity risk is limited by the availability of external financing.



### *Currency Risk*

The majority of sales are concluded in U.S. dollars, and as such, the Company is exposed to the exchange rate fluctuations in that currency. As at December 31, 2012, CardioComm Solutions' exposure to currency risk on U.S. dollar is as follows: cash balances of \$75,969, accounts receivable of \$171,260, and accounts payable of \$46,571. The Company has not entered into any foreign exchange contracts to hedge this risk. A foreign currency translation loss was recognized for 2012 of \$12,607 (2011 – gain of \$5,314).

### **Disclosure Controls and Procedures**

As at December 31, 2012, CardioComm Solutions' management evaluated the effectiveness of the design and operation of its disclosure controls and procedures as defined under the rules adopted by the Canadian securities regulatory authorities. In addition, the Company's management has assessed whether, during the 2012 fiscal year, there have been many significant changes in the Company's internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Disclosure controls and procedures designed to ensure that information required to be disclosed in reports filed with securities regulatory authorities is recorded, processed, summarized, and reported on a timely basis, and is accumulated and communicated to the Company's management, including the CEO and CFO as appropriate, to allow timely decisions regarding required disclosure. Internal control over financial reporting is a process designed by, or under the supervision of, senior management to provide reasonable assurance regarding the reliability of financial reporting and preparation of the Company's financial statements in accordance with International Financial Reporting Standards.

CardioComm Solutions' management, including the CEO and CFO, does not expect that the Company's disclosure controls or internal control over financial reporting will prevent or detect all material misstatements due to error or fraud. Because of the inherent limitations of all control systems, an evaluation of controls can only provide reasonable, not absolute assurance, that all control issues and instances of fraud or error, if any, within the Company have been detected. Based on the evaluation of disclosure controls, and assessment of changes in internal control over financial reporting, CardioComm Solutions' CEO and CFO have concluded that, subject to the inherent limitations noted above, its disclosure controls are effective in ensuring that material information relating to the Company is made known to management on a timely basis, and was fairly presented in all material respects in the Company's Management Discussion and Analysis (MD&A) filing on April 30, 2013.

Based on their evaluation, the CEO and CFO have concluded that the design of these internal controls over financial reporting and the preparation of financial statements for external reporting at December 31, 2012, are effective, except as following: the Company relies on compensating controls, including substantive periodic review of the financial statements, to ensure that disclosure controls and procedures are effective. CardioComm Solutions continues to address requirements to strengthen audit and financial controls.

### **Potentially Difficulty Trading of the Company's Common Stock**

The market price of CardioComm Solutions' common stock has fluctuated and is likely to continue to be volatile. To date, while the trading of the Company's common stock has occurred on a daily basis, its volume been relatively low and significant price fluctuations can occur as a result, which could lead to losses by investors. An active public market for CardioComm Solutions' common stock may not easily develop or be sustained. If low trading volumes continue, price fluctuations could occur in the future and the sale price of the Company's common stock could decline. Investors may therefore have difficulty selling their shares.

The trading price of the Company's common stock may fluctuate in response to factors, such as those listed below:

- actual or anticipated variations in CardioComm Solutions' operating results;
- announcements of developments by the Company or its competitors, including announcements of acquisitions, partnerships, joint ventures, or capital commitments, as well as the introduction of new products;
- regulatory actions regarding CardioComm Solutions' products;
- adoption of new accounting standards affecting CardioComm Solutions' industry;
- additions or departures of key personnel;
- sales of the Company's common stock or other securities in the open market; and
- other events or factors, many of which are beyond CardioComm Solutions' control.

As well, stock markets themselves are subject to significant fluctuations, which could affect the trading price of CardioComm Solutions' common stock. In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been initiated against such company. Litigation initiated against CardioComm Solutions, whether or not successful, could result in substantial costs and diversion of management's attention and resources, which could harm CardioComm Solutions' financial condition.

The Company believes that it has been diligent on solidifying its infrastructure for the patent-pending SMART Monitoring service technologies and building an infrastructure to meet global interest. It has developed a new version of GEMS™ Home, which is expected to be released around the time of this publication, negotiations for distribution channels in North America and overseas continue, production facilities are established, and the Company is undertaking strategic relationships with device manufacturers and international health service groups to leverage the Company's technologies and enable new ECG monitoring devices to come to market.

#### **Potential Dilution of Ownership Interests**

In the future, CardioComm Solutions may issue additional authorized equity securities, resulting in the dilution of the ownership interests of present stockholders. Should CardioComm Solutions reach positive cash flow sufficient to raise stock market price above one dollar, the Company would entertain a private placement financing opportunity to raise sufficient reserves to move to a different trading platform. A maximum dilution target of 200 million common shares, once profitable, would represent a maximal dilution target for a company such as CardioComm Solutions.

CardioComm Solutions may also issue additional shares of its common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, future acquisitions, future sales of CardioComm Solutions' securities for capital raising purposes, or for other business purposes. The future issuance of any such additional shares of common stock may create downward pressure on the trading price of the Company's common stock. There can be no assurance that CardioComm Solutions will not be required to issue additional shares, warrants, or other convertible securities in the future in conjunction with capital raising efforts, including at a price (or exercise price) below the price at which shares of the Company's common stock are currently traded.

#### **Cash Dividends**

The Company is not currently paying cash dividends on its common stock. It is currently anticipated that CardioComm Solutions will retain earnings, if any, for use in the development of its business and the Company does not anticipate paying any cash dividends until the tax credits from its carry forward tax losses have been utilized.

## Glossary

**Affordable Care Act**—Officially titled “The Patient Protection and Affordable Care Act,” this federal healthcare reform statute was signed into law in March 2010. Among its provisions, it expands Medicaid eligibility, establishes health insurance exchanges, and prohibits health insurers from denying coverage due to preexisting conditions.

**Application Service Provider (ASP)**—Web-based applications that do not require a physician to own or maintain a server. The software and database contents (patient data) are remotely stored, backed-up, serviced, and upgraded by the vendor.

**Arrhythmia**—A condition in which the heart beats with an irregular or abnormal rhythm.

**Atrial Fibrillation (AF)**—An abnormal rhythm of the heart that can result in an increased risk of stroke due to the formation of blood clots in the heart.

**Bradycardia**—A heart rate that is abnormally slow. Bradycardia is commonly defined as fewer than 60 beats per minute or a rate that is too slow to physiologically support a person and their activities.

**Calipers**—Instruments for measuring the distance between two points.

**Cardiac Event Monitoring**—Recording a patient’s heart rhythm when he or she is experiencing symptoms (e.g., dizziness, palpitations, shortness of breath, fainting spells, or chest pain) to discover what is causing the symptoms. Since an irregular heartbeat might not last long enough to show up on an ECG, cardiac event monitoring can help pinpoint the cause when the heartbeat irregularity occurs. Like Holter monitoring, event monitoring involves wearing a very small, portable, ECG recorder over a period of time that can vary from weeks to months. When a patient is having an event, he or she just pushes a button to record what is happening with the heart. The recorded data can be sent over the phone to doctors for analysis.

**Cardiomyopathy**—A weakening of the heart muscle (myocardium) that usually causes inadequate heart pumping. It can be caused by viral infections, heart attacks, alcoholism, and long-term and severe hypertension (high blood pressure).

**Chronic Obstructive Pulmonary Disease (COPD)**—A lung disease in which the airways in the lungs produce excess mucus resulting in frequent coughing. Smoking accounts for 80% to 90% of the risk for developing COPD.

**Class I and II Medical Products**—The U.S. Food and Drug Administration (FDA) recognizes three classes of medical devices based on the level of control necessary to assure safety and effectiveness. Class I devices present minimal to no harm to individuals and are usually simpler in design from Class II and III devices. Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments. Class II represents medical devices for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls. Examples of Class II devices include powered wheelchairs, infusion pumps, surgical drapes, and fetal dopplers.

**Class I Medical Device**—See *Class I and II Medical Products* definition below.

**Class II Medical Device**—See *Class I and II Medical Products* definition below.

**Current Procedural Terminology (CPT)**—A medical code set of physician and other services that are maintained and copyrighted by the American Medical Association (AMA) and adopted by the Secretary of HHS as the standard for reporting physician and other services on standard transactions.

**Electrocardiogram (ECG)**—A test used to determine the type of heart rhythm and detect any injury to the heart tissue. During the test, electrodes are placed on the chest to detect the heart's electrical activity.

**Electronic Medical Record (EMR)**—An individual medical record that has been digitized and stored electronically.

**Electrophysiology (EP)**—The branch of physiology that deals with the electrical phenomena associated with nervous and other activity.

**Global System for Mobile (GSM) Communications**—The digital wireless telecommunications standard used throughout Europe and Asia and in select areas of the U.S.

**Health Insurance Portability and Accountability Act of 1996 (HIPAA)**—Legislation passed in 1996 that includes a privacy rule creating national standards to protect personal health information.

**Health Protection Branch (Canada)**—The Health Protection Branch is responsible for developing and implementing legislation, policies, and programs in the area of environmental health protection.

**Holter Monitoring**—Electrocardiogram monitoring done over time, usually over a 24-hour period.

**Implantable Cardioverter Defibrillator (ICD)**—A device implanted in the chest and connected to the heart that delivers a shock to stop a potentially deadly rhythm and restore a normal (sinus) rhythm.

**ISO 13485 Certification**—Specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and regulatory requirements applicable to medical devices and related services.

**QT Interval**—A measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. A prolonged QT interval is a risk factor for ventricular tachyarrhythmias and sudden death.

**Sudden Cardiac Arrest**—A cardiac event similar to a heart attack. It occurs when the electrical system to the heart malfunctions and the heart beats dangerously fast. Blood is not delivered to the body in a sudden cardiac arrest, and the lack of blood flow to the brain can cause unconsciousness and death.

**Sudden Cardiac Death**—A sudden, unexpected death caused by loss of heart function (sudden cardiac arrest). It is the largest cause of natural death in the U.S., causing about 325,000 adult deaths in the U.S. each year. Most sudden cardiac deaths are caused by abnormal heart rhythms called arrhythmias.

**Tachycardia**—An abnormally rapid heart rate.

**Telehealth**—The use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration.

**Telemedicine**—The remote diagnosis and treatment of patients by means of telecommunications technology.

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## CRYSTALRESEARCH ASSOCIATES

### EXECUTIVE INFORMATIONAL OVERVIEW<sup>®</sup>

**About Our Firm:** Crystal Research Associates, LLC ([www.crystalra.com](http://www.crystalra.com)) is an independent research firm that has provided institutional-quality research on small- and mid-cap companies for the past decade. Our firm's unique and novel product, the Executive Informational Overview<sup>®</sup> (EIO), is free of investment ratings, target prices, and forward-looking financial models. The EIO presents a crystal clear, detailed report on a company (public or private) in a manner that is easily understood by the Wall Street financial community. The EIO details a company's product/technology/service offerings, market size(s), key intellectual property, leadership, growth strategy, competition, risks, financial statements, key events, and other fundamental information.

Crystal Research Associates is led by veteran Wall Street sell-side analyst Jeffrey Kraws, who is well known by the international financial media for his years of work on Wall Street and for providing consistent award-winning analyses and developing long-term relationships on both the buy-side and sell-side. He has been consistently ranked on Wall Street among the Top Ten Analysts for pharmaceutical stock performance in the world for almost two decades as well as ranked as the Number One Stock Picker in the world for pharmaceuticals by Starmine and for estimates from Zacks. Additionally, Mr. Kraws has been 5-Star ranked for top biotechnology stock performance by Starmine.

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