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Zacks Small-Cap Research

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Chromedx Corp (MNLIF-OTC)

MNLIF: Initiation report

Current Recommendation	**Hold**
Prior Recommendation	N/A
Date of Last Change	10/15/2014
Current Price (10/16/14)	$0.16
Six- Month Target Price	**$0.55**

OUTLOOK

ChroMedX Corp is in the process of commercializing medical devices with disruptive technology in the In-Vitro Diagnostics (IVD) and Point-of-Care (POC) markets. The company has developed a hand-held unit that is a combination of a blood-gas analyzer and a co-oximeter. ChroMedX's other device offers a novel method of rapid sample preparation for measurement of free therapeutic drugs and hormones, using the existing immunoassays.In the following pages we describe the technology in detail. Currently we are waiting on the products to hit the market and that keeps us at a Hold rating.

SUMMARY DATA

52-Week High	**0.19**
52-Week Low	**0.16**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**143**
Shares Outstanding (mil)	**35.9**
Market Capitalization ($mil)	**$5.7**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**Small-growth**
Industry	**Medical Devices**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					$0.00 E
2015					$0.00 E
2016					$2.10 E
2017					$5.70 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2014					-0.02 E
2015					-0.04 E
2016					-0.02 E
2017					-0.002 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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SNAPSHOT

ChroMedX Corp., formerly operating as Monarch Energy Ltd. disposed of its mineral, oil and gas properties, and is currently focused on the development of novel medical devices for in vitro diagnostics (IVD), specifically in point-of-care testing (POCT). The devices dealing with blood collection, analysis and plasma/serum processing are protected by issued U.S. and pending international patents. ChroMedX (CSE:CHX / USA - OTC:MNLIF) commenced trading at the beginning of July 2014 and formerly traded as Monarch Energy Ltd until formal name change occurred at end of August 2014. On June 30, 2014 the company announced the completion of a capital raise of gross proceeds of approximately CDN $517,500. On September 22, the Company announced the completion of an additional oversubscribed capital raise of CDN $614,500. ChroMedX has 35 million shares outstanding as of this report date

ChroMedX has designed a compact, portable, fully automated POCT clinical analyzer, the HemoPalm^{TM} device that is designed to accept single-use cartridges. The HemoPalm single-use cartridge accepts blood directly from either a finger prick or a syringe. The cartridge containing a patient's blood sample and having an optical chamber as well as biosensors, is inserted into the handheld reader for measurement of CO-oximetry (several hemoglobin species), blood gases (pH, partial pressures of oxygen [pO_2] and carbon dioxide [pCO_2]), and electrolytes (sodium, potassium, chloride, and bicarbonate). These measurements provide rapid assessment of a patient's blood oxygenation and acid-base status, which is of particular importance for first responder patient evaluation and in critical care units in healthcare facilities. The CO-oximetry element of the disposable cartridge uses spectroscopic technology and this element provides the major competitive advantage over all the hand-held devices on the market. To be clear, the major competitors use biosensors only, and the advantages of adding spectroscopy will be explained later.

The Automated Ultra Filtration (AUF) technology also employs single-use disposable cartridges to process plasma or serum to measure therapeutic drugs and hormones that are unbound to proteins (i.e., the "free" drugs and hormones). The medical community understands that the "free" drugs and hormones are biologically active, should be monitored instead of the "total" drugs and hormones. To be clear, the drugs and hormones bound to proteins are not biologically active.

The company is led by an experienced management team. Wayne Maddever, the Director, President and Chief Executive Officer of ChroMedX, has a Ph.D. in Metallurgical and Materials Science Engineering from University of Toronto. He specializes in management of early stage technically based private and public companies and has over twenty five years of experience in commercializing technologies. He is the author of numerous papers in a variety of fields and holds several patents. James Samsoondar is a clinical biochemist and the Director and Chief Science Officer of ChroMedX. Some of Dr. Samsoondar's inventions have been licensed and sold to leading medical diagnostic companies and incorporated in labs.

ChroMedX has commenced development of prototype devices as the first step towards the U.S. Food and Drug Administration (FDA) and Health Canada approval of the technologies. Recently, ChroMedX entered into an alliance with ALine Inc. as its primary contractor for the development of the HemoPalm cartridge and analyzer technology. This move provides significant headway to get the ball rolling for ChroMedX. The goal is to complete construction of the prototype cartridge and an analyzer for demonstrating functionality of the system by the first quarter of 2015.

Considering that there are direct competitors with well-established technologies enjoying a significant market share, ChroMedX faces strong barriers to entry. Hence they will need a clear vision, focused effort and additional capital to bring the comprehensive handheld device to market in the near term.

BACKGROUND

ChroMedX Corp. recently commenced business in the IVD and POCT field. Blood gas analysis hails as one of the preferred patient monitoring systems but the limitations of parameters calculated from those that are actually measured need to be understood. As already mentioned, HemoPalm integrates full CO-oximetry, measured through spectroscopy (the only method for CO-oximetry) which allows the user to measure total hemoglobin (Hb), Oxy-Hb, Deoxy-Hb, Met-Hb and carboxy-Hb simultaneously with blood gases and electrolytes measured with biosensors.

CO-oximetry has traditionally been performed using bench-top analyzers that are large, expensive and usually located in central laboratories. There are many benefits to providing these blood tests near or at the point of care of patients (discussed later in this report) but these are usually limited by the size and cost of the analyzers. More recently, blood gas analyzers have shrunk in size while increasing their capabilities such as an expanded menu of measurements, quicker, more accurate results with less operator intervention, and growing compatibility with electronic medical records systems.

Therefore, to address the need for POCT devices at emergency rooms (ER), operating rooms (OR) and intensive care units (ICU), neonatal intensive care units (NICU), and emergency first responder teams, ChroMedX offers a handheld device for such applications that require ease of use combined with low maintenance. The ChroMedX system is comparable with the larger lab analyzers that combine spectroscopy and biosensor technologies. On the other hand, the existing handheld analyzers do not offer this combination of full CO-oximetry measurement using spectroscopy and biosensors. Further, existing handheld devices use conductivity rather than spectroscopy to measure hematocrit, from which the Hb is calculated thereby compromising the accuracy of the Hb results, and cannot measure Oxy-Hb, Deoxy-Hb, Met-Hb and Carboxy-Hb. The hematocrit measurements are reliable in most clinical settings where there are no large variations in protein concentrations, abnormally increased lipids (fats), and abnormal blood cells, which is the case of most seriously ill patients. The second important distinction is that the HemoPalm actually measures hemoglobin oxygen saturation (sO_2) by CO-oximetry; the competitors calculate sO_2 from the pO_2, thereby providing a very misleading assessment of blood oxygenation in for example, a victim of smoke inhalation of carbon monoxide poisoning (Carboxy-Hb will be elevated). Another example is a baby treated with nitric oxide for respiratory distress, who will exhibit elevation of Met-Hb.

ChroMedX attempts to provide a solution in the diagnostic space by combining two existing technologies into one handheld unit. ChroMedX's devices are mainly characterized by quantitative single measurements, short turnaround time, no pipetting, use of pre-made reagents, and user-friendly dedicated analytical instruments. Since the analyzer is handheld it can be used within close proximity to the patient where diagnosis can be made immediately. Enhanced functionality of ChroMedX's multianalyte critical care device that employs single-use cartridge and the increasing demand for blood gas testing at the bedside continues to provide opportunity for ChroMedX and may encourage health care facilities to replace conventional lab-based instruments.

ChroMedX also offers a novel method using ultrafiltration to separate proteins from plasma to facilitate the analysis of free hormones and therapeutic drugs that are unbound to proteins for immunoassays. The single-use AUF cartridge is designed to have capability to prepare immunoassay samples in less than one minute.

Intellectual Property

Trade Mark

Serial Number	Country	Mark
86/150719	US	HemoPalm

Issued Patents

Patent No.	Title	Filing Date
US Pat. No. 8,206,650	Joint-Diagnostic Spectroscopic and Biosensor Meter	May, 2, 2006
US Pat. No. 8,101,404	Plasma Extraction Apparatus	Oct 4, 2010
US Pat. No. 7,816,124	Diagnostic Whole Blood and Plasma Apparatus	May 12, 2006
US Pat. No. 7,807,450	Plasma Extraction Apparatus	Aug 8, 2007
US Pat. No. 7,740,804	Spectroscopic Sample Holder	Jan 18, 2008

Pending Patents

Patent Application No.	Title
PCT/CA2013/050935	Automated Ultra-filtration System
US Pat. App. No. 13/549,443	Sample Filtration Assembly
US Pat. App. No. 62/006066	Joint Spectroscopic and Biosensor System for Point-of-care Testing



HemoPalm™ analyzer and cartridge provide full co-oximetry plus blood gases

HemoPalm™ - Blood sampling technology

Clinicians and ER/OR personnel use blood gas analyzers to measure the level of various hemoglobin species, blood gases pO_2 (arterial oxygen tension), pCO_2 (carbon dioxide tension), and the acid base

status (pH) in patients to obtain an accurate understanding of the patient's oxygenation status to help aid in disease diagnosis and treatment. Critical care systems obtain results for the electrolytes that are most likely to be monitored during clinical care. There is true value in determining a patient's hematocrit and hemoglobin species since paramedics can use these to monitor an acute or chronic condition. There is real benefit to being able to measure blood gases as paramedics who treat patients with chronic breathing disorders may be able to catch worsening conditions earlier and allow physician intervention before more intensive care is necessary. The POC devices are typically used in the ICU, NICU, cardiac catheterization laboratories, and respiratory care services, critically-ill patients undergoing circulatory shock, accidents involving hemorrhage and other emergency situations.

Tissues need a requisite amount of oxygen molecules for metabolism. The oxygen content provides information on the number of oxygen molecules that are present in the blood. Whole blood is comprised of both plasma and red and white blood cells. Hemoglobin is the main chemical substance within red blood cells and is the compound which transports the major portion of oxygen to the tissues. Oxygen molecules are found as either free molecules dissolved or bound to hemoglobin in blood. Spectroscopic measurement of hemoglobin and hemoglobin oxygen saturation provides the best measurement of a patient's oxygenation status. Oxygen saturation calculated from pO_2 is critiqued because pO_2 represents the oxygen dissolved in the blood plasma, which accounts for only about 1% of the total oxygen in blood. The remaining 99% of blood oxygen is bound to hemoglobin. To determine the amount of oxygen that is bound to hemoglobin, hemoglobin oxygen saturation and hemoglobin content are measured. The ferrous porphyrin portions (heme sites) of the hemoglobin molecule serve as the binding sites for oxygen. There are four heme sites per hemoglobin molecule, and hence four oxygen binding sites. Heme sites occupied by oxygen molecules are said to be "saturated" with oxygen. The percentage of all the available heme binding sites saturated with oxygen is the hemoglobin oxygen saturation (in arterial blood). The oxygen that is bound to hemoglobin can only be measured using wave lengths of light (spectroscopy) and is measured on a co-oximeter that test for the various hemoglobin species.

The pO_2 is usually measured on a blood gas analyzer along with pH and pCO_2 measurements. The pO_2 is an indication of the pressure of oxygen dissolved in the blood, and the ease of movement of oxygen from the lungs into the blood. Since pO_2 reflects only free oxygen molecules dissolved in plasma and not those bound to hemoglobin, pO_2 measurement does not reflect the total amount of oxygen that is in the blood. The pCO_2 is an indication of the pressure of carbon dioxide dissolved in the blood, and the ease of movement of carbon dioxide out of the body. The pH determines whether the patient is in an acidic or alkali state. Electrolytes help maintain osmotic pressure, in the regulation of heart function and other muscular contraction, in maintaining oxidation-reduction potential, and participate as catalysts for enzymes. Disturbance of potassium (K) homeostasis causes muscle weakness and affects the heart rate. Sodium (Na) maintains normal distribution of water through osmotic pressure.

Currently pulse oximeters are widely used to measure hemoglobin oxygen saturation as they are inexpensive, continuous and portable. Abnormal movement of blood flow, such as an increase in venous pulsation, low arterial blood flow, hypotension, vasoconstriction and hypothermia reduces the pulsatility of capillary blood and may cause interference with oxygen saturation measurement. However, the accuracy of the pulse-oximeter declines when the oxygen saturation falls below 90%. Further, the use of pulse oximeters is limited since they are designed to measure oxygenated and deoxygenated hemoglobin, but no provision is made for measurement error in the presence of carboxyhemoglobin (CO-Hb, measurement of carbon monoxide poisoning) and metaemoglobin (Met-Hb). Hence, in such situations CO-oximeters are designed to measure reduced hemoglobin, hemoglobin oxygen saturation, CO-Hb and Met-Hb. In addition pulse oximeters provide no information on blood gases, pH or electrolytes thereby providing only partial information.

CO-oximetry measurement by spectroscopy is considered the gold standard for determination of hemoglobin oxygen saturation[1]. A CO-oximeter distinguishes oxyhemoglobin from carboxyhemoglobin and determines the hemoglobin oxygen saturation even as the patient has compromised oxygen levels.

[1] M Moiter, Does Every Blood Gas need CO-oximetry?, Respiratory Therapy (Special supplement 2009)

Other techniques that rely on conductivity measurement via bio sensors to calculate the hemoglobin content may produce inaccurate results when certain clinical conditions are present.

While the gold standard for hemoglobin and blood gas testing is generally considered to be arterial blood sample collected anaerobically from an arterial catheter (usually radial artery from an adult, or perhaps umbilical in a neonate) or arterial puncture, the sample obtained from the artery is somewhat difficult, painful, and dangerous than routine venipuncture. Therefore, attention has been directed towards obtaining blood by less painful and risky procedures. Since venous blood is not a satisfactory substitute for arterial blood for routine blood gas testing, capillary blood sampling has been investigated. Capillary blood gas analysis is particularly desirable in neonates, for whom vascular access can be challenging and for whom blood collection with standard approaches can withdraw volumes of blood that are unacceptably large relative to the total blood volume present. The conventional blood sample holder exposes the blood to atmospheric oxygen thereby falsely increasing and decreasing the oxy-hemoglobin and the deoxy-hemoglobin respectively. ChroMedX has designed a patented sample holder that prevents the exposure of blood to atmospheric oxygen. The holder can be filled with a syringe (blood from an arterial line), or it can be fitted with a capillary tube inlet for drawing capillary blood.

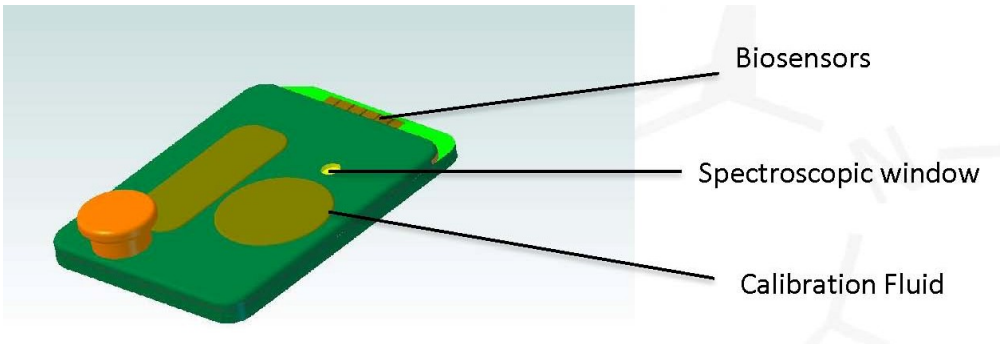
The HemoPalm device currently consists of two cartridges:

- HemoPalm to measure CO-oximetry, blood gases (pO2, pCO2, pH) and electrolytes (K, Na, Cl)
- HemoPalm B to measure neonatal bilirubin

A third cartridge which will measure lactate is in the initial stages of development. Lactate is a measure of sepsis (blood poisoning) which is very common and dangerous in the Emergency Department

HemoPalm cartridge:

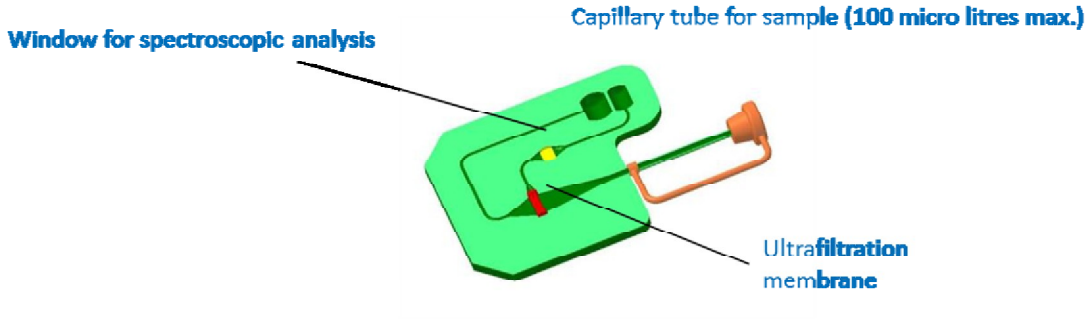
Hemoglobin species is measured by CO-oximetry (spectroscopy), and blood gases and electrolytes are measured using biosensors. Thus the HemoPalm provides a unique solution to blood analysis by offering a complete solution in a hand-held device. The HemoPalm device comprises of an analyzer and a disposable cartridge for analyzing blood sample that is drawn into the cartridge via a single pin prick to provide spectroscopic and biosensor diagnostic measurements at the POC without requiring access to central laboratory facilities, or any sample preparation. The HemoPalm is designed to provide measurements of total Hemoglobin (Hb), Oxy-Hb, Deoxy-Hb, Carboxy-Hb, Met-Hb, Hemoglobin oxygen saturation, blood gases, pH and electrolytes (Na, K, Cl).



HemoPalm B cartridge:

High blood concentrations of bilirubin are a symptom of jaundice and are toxic to the brain and may cause kernicterus, a condition of irreversible neurologic damage caused by unconjugated bilirubin. Therefore, determination of bilirubin levels is performed for many neonates. Approximately 15% of all neonates will develop jaundice. Drawing blood is painful, time consuming and an expensive procedure. In addition, it

leads to stress for both the infant and the parents. The HemoPalm B device offers a convenient choice for near-patient bilirubin determinations from blood sample obtained from heel/finger pin prick. The optical measurements are directly calculated from unhemolyzed whole blood. This cartridge employs ultrafiltration to separate plasma from the blood sample followed by spectroscopic analysis of the plasma for bilirubin.



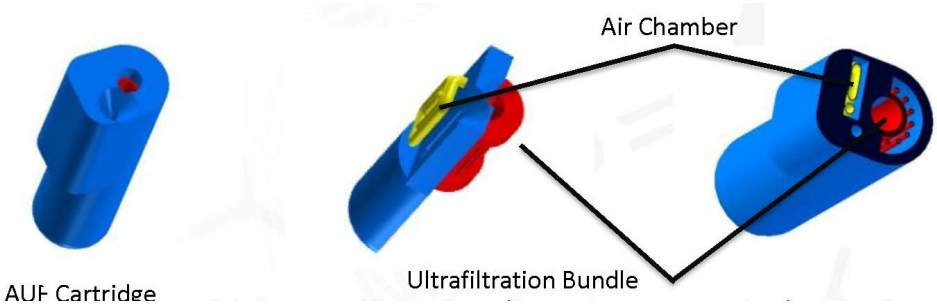
HemoPalm B Cartridge

Automated Ultrafiltration technology (AUF) - Blood collection and Plasma extraction

Serum or plasma is used to determine the concentration of hormones or therapeutic drugs obtained from the patient's blood. The tests are performed using immunoanalyzers in laboratories. These devices are only capable of measuring the total amount of these hormones or drugs in the plasma. However, the vast majority of these chemicals species are attached to proteins in the blood system thereby rendering them inactive. Only the free floating chemical species (the biologically active form) does the work in the body. . The development of immunoassays for the detection of free hormones and therapeutic drugs are difficult and expensive. In order to measure the free species, the proteins in the plasma sample must be removed. About eighteen hours are required to perform equilibrium dialysis, and thirty minutes is required for membrane centrifugation to separate the proteins from the plasma

Equilibrium dialysis is based on establishing an equilibrium state between two chambers, one containing plasma containing drug and the other a buffer solution with no drug, that are separated by a semipermeable membrane. During the incubation period the free drug molecules cross over to the buffer solution

Ultrafiltration is a technique to separate extremely small particles and dissolved molecules in fluids. The primary basis for separation is molecular size, although other factors may contribute in the separation process. Protein purification by ultrafiltration process is widely adopted in the medical community. The hollow fiber cartridges are easy to use and the gentle flow path within the hollow fiber is shear-sensitive thereby rendering higher yield.



ChroMedX provides an alternative to rapidly modify the sample in a proprietary disposable cartridge that can be presented to the existing immunoanalyzer. The AUF technology employs a novel automated

system of ultrafiltration that attempts to replace the existing centrifugation techniques that are manual and time consuming. Samples, prepared using ultrafiltration, are free of chemical species bound to proteins and thus the measurement yields only the free hormone or drug. The rapidity and automation of the AUF technology promises to alter the way therapeutic drugs are monitored, and the way hormone-related disorders are diagnosed and treated. Proof of concept for this technology has been demonstrated by ChroMedX. All of ChroMedX's technologies have been issued U.S. patents except for the AUF technology that has a pending application.

Plasmapheresis is a separation process to remove plasma from whole blood, often done for analysis. Conventional method of plasmapheresis has been to use either continuous high speed centrifugation or an ultrafiltration using membranes to separate cellular components from plasma. In the ultrafiltration method whole blood passes through a semi-permeable membrane of hollow fibers of specific pore size to retain red and white cells as well as platelets while allowing immunoglobulins to pass through. ChroMedX has patent on the Plasma Extraction Cartridge (PEC) that performs the separation of plasma from whole blood during sample collection using the ultrafiltration technology. Currently, the standard practice is collection of whole blood in a vacutainer that undergoes centrifugation to separate plasma from red blood cells. Therefore the AUF/PEC product family represents a novel technology in the market.

The Evolving Diagnostics Landscape:
The recent advancements in medical testing have revolutionized the gamut of in-vitro diagnostics. Patients undergo tests, not only for merely diagnosing but for determining the best suited therapy for the specific condition. A wide range of POCT devices currently in the market strongly emphasize that diagnostics seem to have literally gone from bench to bedside. Additionally, POCT ensures rapid results, better patient compliance and reduces repeated visits to a centralized laboratory.

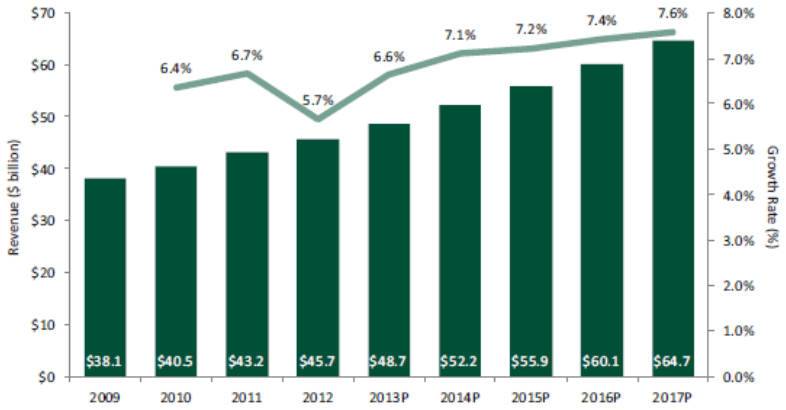
One of the key concerns within the healthcare sector was the challenge in overcoming snowballing healthcare costs. However, the diagnostics segment continues to remain most cost efficient compared to other segments of medicine. The requirement for point of care testing is expected to further tilt in favor of the diagnostics domain as the demand for more rapid laboratory services increases within clinical practice. Pre-hospital care and critical care transport employ POCT to improve patient care and reduce overall healthcare costs. Currently, the diagnostics industry is experiencing a watershed effect and by delivering value-driven care that allows early interventions, offer personalized treatment, reduce hospitalization and the related charges helps bridge the gap in a patchy healthcare environment.

The IVD market is valued at $16 billion. The IVD market is primarily dominated by bench-top laboratory analyzers and POCs. Although POC forms a smaller portion of this market (12% of IVD), nevertheless, POC is a growth market. Testing at the POC has several advantages over central laboratory testing, specifically decrease in total turnaround time and being able to identify the patient with their sample with RFID tags/bar codes. The ensuing increase in the number of elderly individuals, aged over 60 years, are prone to various chronic conditions that require therapeutic intervention, which in turn requires in-home testing of various biological parameters. With the increase in number of clinical procedures, adoption of testing devices is also on the rise. Growth is also fueled by a number of other factors such as improvements in technology, incorporation of integrated technologies in hematology analyzers, launch of new and automated POC analyzers.

The POC market includes all areas where a patient is assessed or diagnosed such as in critical care settings, alternative care settings, physician offices, rapid-response laboratories, patient health screening locations, long-term care facilities and for in-home monitoring of patients with chronic conditions. POC devices have proven successful for three reasons: menus on these models have been expanded to include the most urgent critical care analytes with a fast turnaround time; all the systems accept whole blood as a sample and require little or no maintenance; and most have integrated, automated quality control features. Within POCT devices, blood gas analyzer market is expected to grow at a CAGR of 13.5% (Frost & Sullivan, March 2010).

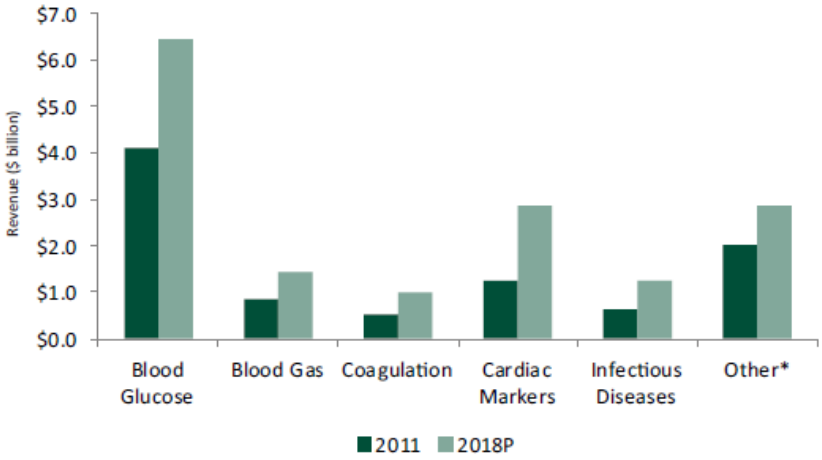
Global IVD Market

Total IVD Market, Global Revenue Forecast



Point of Care Testing Market

Global Revenue Forecast



(Source: BGL Healthcare and Life Sciences: Diagnostics, December 2013)

The POC diagnostics market is very diversified and comprised of infectious diseases testing kits, glucose monitoring kits, coagulation monitoring kits, hematology testing kits, cardiac markers, blood gas/electrolytes testing kits, and several others. The POC diagnostics market (excluding blood glucose monitoring kits) is dominated by Roche Diagnostics Ltd. (Switzerland), Alere Inc. (U.S.), Siemens AG (Germany), and Beckman Coulter, Inc. (U.S.).Geographically, North America commands the largest market share of more than 50% of the global POCT devices in 2013, followed by Europe as per markets and Markets global research company. The Asia-Pacific region is poised to grow at a high rate, owing to factors such as large patient population, and growing focus of both international and domestic players.

Competitors for the HemoPalm device:

Presently, no single point-of-care testing system can test every electrolyte. Having mentioned that, ChroMedX's direct competitors in the clinical chemistry space are Abbott's i-STAT system and Alere's epoc Blood Gas Analysis System. One of the most successful examples of POC diagnostics using microfluidics and micro-fabricated devices is the i-STAT System from Abbott Point of Care, Princeton, NJ. It is a single-use, cartridge-based system that has an extensive menu (19 determinations and six calculated results). There are 18 different cartridges with numerous combinations of tests. For all cartridges requiring calibration (chemistries and blood gases), a one-point calibration is performed automatically as part of the cartridge testing cycle. No sample dilution or pretreatment is needed. The analyzer consists of a motor that controls flow of calibrant and sample within the cartridges, an electrical connector to receive signals from the cartridges, an electronic system to measure and monitor signals from the micro-fabricated thin-film electrodes, and an LCD display as user interface. The Abbott service center can perform diagnostics through a modem.

The analyzer was approved and introduced into the U.S., and has since been considered one of the gold standards of POC diagnostic equipment. The Abbott i-STAT handheld system's ease of use, wide range of analyte measurements, portability and result storage/transfer capacity make it favorable to use by one in three emergency departments in the U.S. i-STAT's CHEM8+ cartridge measures electrolytes (Na, K, Cl, ionized Ca), CO_2, anion gap, glucose, creatinine, urea nitrogen, hematocrit and hemoglobin. All i-

Device	HemoPalm	Hemocue	i-Stat	Avoximeter	TruPoint	Epocal	Benchtop	ABL77/90 Flex	Rapidpoint 400/500	Radical 7
Manufacturer	ChroMedX	Hemocue	Abbott	ITC	ITC	Alere	Various	Radiometer	Siemens	Massimo
Device										
Disposable Sample Cartridge										
Handheld	YES	NO	YES	X	NO	YES	NO	NO	NO	*6
Sample Method	pin prick or syringe	syringe	syringe	syringe	syringe	syringe	syringe	syringe	syringe	non-invasive finger monitor
Can Capillary Blood be used directly	YES	NO *3	NO *4	NO	NO	NO	NO *4	NO *4	NO	NO
Analysis Method	Optical + Biosensor	Optical	Biosensor	Optical	Biosensor	Biosensor	Biosensor/ Optical	Bio (77)/ Opt (90)	Bio(400)/ Opt (500)	Optical
Risk of Atmospheric Contamination	NO	Not Applicable	NO *5	NO	NO	NO	NO	NO	NO	Not Applicable
Full Co-oximetry (4 Hb species + Total Hb)	YES	Total Hb only	NO	YES	NO	NO	YES	YES	YES	NO
Measures Total Hb	YES	YES	*1	YES	*1	*1	YES	YES	YES	*1
Measures sO2	YES	NO *3	*2	YES	*2	*2	YES	YES	YES	*2
Electrolytes	YES		YES	YES	YES	YES	YES	YES	YES	NO
Blood gases	YES	NO *3	YES	YES	YES	YES	YES	YES	YES	NO

Footnotes:

1. Calculates Total Hb from Hemocrit (Errors in both the Hb calculation and Hct measurement)
2. Calculates sO2 from pO2 (Errors in calculation)
3. Pinprick sample can be used, but the sample must be placed on a slide for pickup by the cuvette
4. Pinprick can be used, but it must first be collected in a capillary tube
5. Potential air contamination in the transfer step when capillary sample used for blood gas measurement
6. Not applicable because wires have to connect the analyzer to a finger

i-STAT cartridges are capable of measuring arterial blood gas, troponin or lactate levels. I-STAT cartridges have two different storage life limits based on storage conditions: 2 weeks at room temp and 2 months refrigerated.

The Alere-epoc Blood Gas Analysis System, from Alere, Waltham, MA, is a single-test system that can measure nine parameters including arterial blood gas, electrolytes (similar to i-STAT), glucose, hematocrit and hemoglobin, and a lactate level. A one-point automatic calibration is required for every sample. Analysis time is 35 seconds. An interesting feature of Epocal is the ‘‘SmartCard’’ technology and wireless communication capability of the reader and its associated mobile computer, which can interface with a laboratory information system easily. The epoc system has no capability for remote-service diagnostics. The epoc blood analyzer requires no refrigeration.

Regardless of the efforts by the major industry players such as Abbott and Alere to increase market share by acquisition of smaller companies offering novel technology products, the industry remains highly fragmented, leaving room for several small players with innovative platforms and expanding test menus to compete in the POCT space.

How does the HemoPalm Technology stack up against its competitors?

Technology:
ChroMedX tries to address the question: Can HemoPalm provide as much information as possible to the physician so that they can make a good therapeutic choice?
Blood gases, electrolytes, and hemoglobin are analyzed in critical care units in order to monitor patient status. The leading competitors in POCT require a second spectroscopic analyzer to provide CO-oximetry. Spectroscopy is the gold standard for measuring hemoglobin oxygen saturation and total hemoglobin and all of the hemoglobin species. The ability to provide all the measurements described above in a single central laboratory analyzer has been available since the 1990s. Compared to other devices in the marketplace, HemoPalm cartridges and analyzers offer a complete solution for blood collection and analysis. The HemoPalm system is being developed to provide the following benefits which would be unmatched by competitive devices:

- Measurement of blood gases, electrolytes and CO-oximetry via spectroscopy
- Accurate measurements of arterial blood oxygenation without sampling via syringe
- No risk of contamination of sample by air (oxygen)
- Neonatal (bilirubin) measurements (HemoPalm B)

All HemoPalm cartridges are designed to collect blood through capillary action thereby requiring only a small volume of sample to be collected from the patient through a pin prick, although syringe extraction is available as an option for OR settings.

The i-STAT Chem8+ cartridge can measure blood gases, electrolytes, hematocrit and hemoglobin. Unlike the HemoPalm, the i-STAT device employs the conductivity method to measure the hemoglobin species. Conductivity measurements can be strongly influenced by plasma protein and electrolyte concentrations. The HemoPalm uses CO-oximetry, a methodology that relies on the specific light absorption characteristics of each hemoglobin species at selective wavelengths. Also, the i-STAT device requires the use of a syringe to draw arterial blood. This is a distinct advantage for HemoPalm as it requires only a few drops of blood that can be obtained with pin prick from the heel or finger. The shelf-life of the HemoPalm cartridge is expected to last six months at room temperature and longer, possibly up to one year, if it is refrigerated. The expected analysis time is between two to five minutes.

Pricing:
The combination of exceptional sensitivity, high number of simultaneously measured analytes, portability, and extremely low cost (per test) places HemoPalm in a category by itself. Abbott’s i-STAT device costs about $9,000 per analyzer. The ChroMedX device is expected to be priced at $5,000 per analyzer. The low pricing on the unit is expected to provide significant cost savings for the end user. ChroMedX estimates that the average usage per analyzer will be about 1,500 per year.

Market:
The global IVD market is dominated by a few major companies accounting for over 80 percent market share. Beyond these companies that command significant control over the market, the IVD landscape is comprised of smaller companies that make or develop competing or niche IVD/POCT devices.

There's anecdotal evidence that large players in the POCT space are looking to buy smaller diagnostics companies that boast a unique technology advantage. We expect M&A to continue to play an instrumental role in how POC diagnostic companies navigate in a rapidly changing marketplace. In an active deal market, strategic buys amongst industry players will create a means to more rapidly access novel technologies, access various market segments; expand test menus, expand geographic reach; and overall increase market share. Historically, M&A activity of some of the high profile acquisitions resulted in a few players gaining significant scale.

Since 2001, Abbott became a huge healthcare firm by bolstering its diagnostic products business with the acquisition of several smaller companies. Abbott Point-of-Care manufactures diagnostic products for blood analysis. In addition to its excellent product range in the blood gas and chemistries segment, Abbott also provides POC cardiac assays to the ER. Abbott's highly regarded IVD unit as well as the company's POC diagnostics business combined generated about $2.7 billion in sales during 2006.

Alere has widened its rapid diagnostics platform with a string of acquisitions comprised of drug and toxicology screening companies AmMed, Amedica, eScreen in 2012 and Epocal in 2013, a technology that supports blood gas and electrolyte testing at the POC.

Competitors for the AUF technology
In the area of immunoassays, IVD manufacturers continue to see the development of increasingly sensitive detection methods that surpass the limits of detection that can be achieved with traditional immunoassay formats. Unfortunately, many of these new methods require specialized instrumentation that is either not available or not affordable for smaller clinical laboratories. Currently there are no direct competitors for the AUF technology.

Globally the immunoassays market is dominated by seven companies: Roche Diagnostics, Siemens Healthcare Diagnostics, Abbott Diagnostics, Danaher Corporation, Ortho Clinical Diagnostics, bioMérieux, and DiaSorin S.P.A. Put together, these giants account for more than 85% market share. Of these, Roche holds about one-fifth of the overall market share as they offer a broad portfolio of products with more than one hundred assays in various disease categories.

In order to keep pace with the industry, one of the preferred strategies followed by large companies is through acquisitions and partnerships with smaller firms that offer novel technologies. By increasing their product portfolio, the key players can increase market share thereby consolidating their global presence. As per MarketsandMarkets global research firm the immunoassays sector accounts for approximately 25% of the IVD market and was valued at $13 billion in 2013. The immunoassays market is estimated to grow at a CAGR of 8.1% through 2018. The combination of a high single-digit growth rate and large market size offers significant opportunity for participants in the immunoassay segment.

INVESTMENT THESIS

Product's Development Status:
All of ChroMedX's projects are developing in parallel. As per discussions with management, product

prototyping is underway and the company anticipates completion of a prototype of HemoPalm by Q1 2015. The prototype development employing the AUF technology is expected to be completed by end of this year. Clinical trials, which are an important step in the commercialization process as results will determine the marketability of the device, are expected to commence by the end of this year. If ChroMedX's device yields favorable results from the initial clinical trials, management expects to commence marketing initiatives subsequently. As the products are still in relatively early stages in the development process, the visibility on timelines is unclear at this point. We hope to hear more from the company once prototype development is completed.

Regulatory Issues:
The FDA via the 510(k) grants a clearance for sale of the product by determining if the device is substantially equivalent to a predicate device that is already cleared and legally marketed in the U.S. 510(k) clearance is the least stringent and typically shortest regulatory pathway for medical devices to be approved for sales in the U.S. As per research conducted by the Emergo group, it takes on average about five months for the FDA to review and clear a medical device's 510(k) application. ChroMedX believes they will be able to follow the 510(k) regulatory pathway in lieu of the more stringent, more costly and time consuming PMA pathway. There are several predicate devices on the market that the company can choose to provide at the time of the 510(k) filing of which Abbott's i-STAT can be one due to the similarity of intended use.

Since the AUF technology is an analytic process, ChroMedX needs to prove its equivalence to the centrifugation process. Therefore it is not easy to generalize the type of data to show substantial equivalence. The application may need to be supported by other analytical studies that demonstrate precision, repeatability, or a multi-center clinical trial with clinically established end-points that serve as the ultimate determinant of accuracy.

Certain diagnostic tests and instruments used at the point-of-care must also be CLIA (Clinical Laboratory Improvement Amendments) waived given that they are intended to be used outside laboratories that handle complex tests. The CLIA waiver certifies the device as being simple to operate producing accurate results. Obtaining a CLIA waiver requires a separate application to FDA, submitted after obtaining the 510(k) approval for the POC diagnostics device. This requires data from studies involving the intended end-users of the POC device. Of the 200,000 labs in the U.S. roughly 60% have obtained this waiver. Having the waiver allows the manufacturer to make the device (analytes it can test for) available to the widest possible range of end-users.

An equivalent example… Abbott's i-STAT system is CLASS II certified (meaning that the device may have to comply with mandatory performance standards in the future if it is to remain in commercial distribution) . Five components of the Chem8+ cartridge used by Abbott's i-STAT handheld blood analyzer were granted FDA approval, the CLIA waiver as well as a CPT code for medical reimbursement.

Business Strategy:
As there are clearly a significant number of hospitals and first responders, management expects to target these markets first. As per discussions with management, ChroMedX's strategy to bring the products to market will be through engaging distribution channel networks. Once the regulatory approval and clearance are obtained, given the lengthy timeline it may take, it is critical for ChroMedX to have clear sales and marketing objectives to provide commercial appeal.

Aside from the unknowns related to the development and commercialization timelines, the engagement with distributors is yet to be established. Having partnerships with a well-networked distributor is very crucial for ChroMedX as it can have a significant impact on revenues, gross margins and cash flow. Since the company hopes to follow a razor/razorblade revenue model, we can expect that the volume of cartridge sales will be the primary driver of revenues. Further we expect the company to achieve significant sales volumes of cartridges and analyzers primarily due to lower prices as compared to competitor's.

We can then expect the product margin to increase with increasing sales. We expect that the general and administrative costs will remain high in the initial years after product hits the market. We also model expenditures associated with marketing and sales initiatives to remain high as ChroMedX attempts to establish a wide customer base.

As a healthcare technology, POC diagnostics requires significant capital for development and commercialization. Even if ChroMedX's HemoPalm is commercialized by end of 2015, we do not expect the company to reach significant revenues for a few years. Between now and then they are likely to be cash flow negative.

Competitiveness:
While the POC IVD market as a whole is highly diversified, the market specific to IVD POC clinical chemistry is largely controlled by only a few large players, estimated to hold about 60% market share. Taking share against well-established products is difficult due to a variety of factors. The most simple of which is that these proven technologies and products have the benefit of a performance and reliability history (i.e. customers know what to expect from them). Many of the competing analyzers are also well-known brands sold by large corporations with deep pockets sold through vast distribution networks. A majority of these machines also have the ability to run a variety of tests in sequence. Larger testing menus have been cited as a major reason for the expansion of POC testing as a whole over the past decade and clearly it has also been a catalyst in growing market share and minimizing customer churn by the various market participants. The ease and degree of connectivity, or the ability to transfer data to an information system, can also be a major differentiating factor among these POC devices. This type of connectivity has become almost a prerequisite before most hospitals will consider using a particular device. While some of the lesser-known analyzers lack any connectivity at all, ChroMedX plans to provide this level of connectivity for its products.

Abbott's i-STAT handheld device has been the oldest POC device in the market and has been around since 1992. Abbott claims that its device is used in one out of three hospitals in the U.S. It has taken more than a decade to achieve this reach. Before its acquisition by Abbott, i-STAT Corp. was not profitable despite having revenues of more than $50 million. In the initial period of ChroMedX's device launch, we expect a slower adoption rate as clinicians as well as patients approach new devices with uncertainty. This may hamper HemoPalm's ability to penetrate the market, at least initially. It is also important to note that i-STAT offers other cartridges capable of performing additional tests for hematology, coagulation and cardiac markers, potentially offering stiff competition to HemoPalm as ChroMedX will not initially offer cartridges with these capabilities.

Although ChroMedX believes that HemoPalm is capable of competing favorably with the i-STAT or Epocal systems on the basis of ease-of-use, the ability to conduct tests without a skilled technician and the spectroscopic analytical method offering true co-oximetry, we believe they will face barriers to entry for the reasons stated above. However, we believe that ChroMedX can differentiate their product due to superior analytical techniques as well as significantly lower pricing of the analyzer as compared to i-STAT and Epocal and be capable of building a sufficient customer base by extending its reach in regional markets where larger companies are absent.

ChroMedX's device also competes with manufacturers of traditional blood gas analyzers that are in use in clinical laboratories. Historically, most clinical testing has been performed in the hospital/commercial laboratories that provide analyses that combine spectroscopy and biosensor based measurements. They have been effective at processing large panels of tests with the use of skilled technicians and complex equipment. HemoPalm offers a competitive advantage of providing this same combination of technologies at a lower cost, quicker result and at the point-of-care.

Long-Term Growth:
As ChroMedX is a new entrant into the market, they face significant competition from well-established companies. ChroMedX has to continually innovate and bring new technologies to the market constantly. If not, they face the risk of becoming obsolete as their competitors continue to innovate. An expanded and

more diverse testing menu would also provide the company the necessary firepower for additional growth.

VALUATION/RECOMMENDATION

ChroMedX's products are still in the developmental phase and there are a many unknown factors associated with such early stage firms. Therefore, the valuation is not normally intuitive and straightforward due to uncertainties associated with such companies.

Financial Condition:
The regulatory process, even with a 510(k) pathway, can be protracted and costly. We expect R&D expenses and cash burn to increase significantly through 2015 as clinical and FDA trials get underway. As noted, we expect ChroMedX's focus will initially be with bringing HemoPalm and AUF to market with the PEC technology likely on the back-burner for now. We expect operating expenses to remain elevated during the initial years as a result of ongoing R&D and regulatory activities for the HemoPalm and AUF devices. Perhaps conservatively, we model revenue to grow modestly through the end of 2016. Based on our assumptions, ChroMedX should begin to gain traction during the years following 2016 and by 2020, as revenue growth substantially exceeds operating expenses, the company should become cash flow positive.

ChroMedX has completed one round of financing that yielded gross proceeds of about $500,000. On September 22, the company announced the completion of an additional oversubscribed capital raise of CDN $614,500. We expect that ChroMedX will need roughly $1-2 million for prototype manufacturing and testing as well as for initial business development. As such, there are risks of development and regulatory-related delays which may require an infusion of additional capital. The company expects to raise any additional required capital later this year.

Valuation: HemoPalm and AUF are still in the prototype stage. There are a number of uncertainties related to clinical trial outcomes, regulatory approval timelines and capital expenditures. There is a large barrier to entry due to more established players occupying a dominant space in the POC diagnostics market. Entry into the market will be gained by claiming a niche position within clinical chemistry by offering their technology at a significant discount. We do not expect ChroMedX to gain a foothold in the POC diagnostics space right away. Instead we expect HemoPalm to launch in 2016 as per plan to first responders initially. Once ChroMedX technology is established in the market, we think the company will be able to establish a more meaningful customer base. Eventually, we expect it will be easier to increase adoption of their device in other segments of POC market and model modest revenue in 2016 but growth accelerating much more dramatically by 2018. As ChroMedX launches other new test cartridges, including products that are currently under development, it could prompt a revision to our forecast, particularly as it relates to our out-years.

If development and commercialization of their devices pan out as per plan, ChroMedX has the potential to turn cash flow positive in 2018. We use a Discounted Cash Flow (DCF) analysis and we derive the total equity value of approximately $25 million with a target price of $0.55/share. This keeps us at a Hold rating.

FINANCIAL MODEL

	2014 E	2015 E	2016 E	2017 E	2018 E	2019 E
Revenue	$0.0	$0.0	$2,100,000.0	$5,700,000.0	$12,800,000.0	$22,900,000.0
YOY Growth						
Cost of Goods Sold	$0.0	$0.0	$1,100,000.0	$2,950,000.0	$6,600,000.0	$11,750,000.0
Gross Income	$0.0	$0.0	$1,000,000.0	$2,750,000.0	$6,200,000.0	$11,150,000.0
SG&A	$350,000.0	$850,000.0	$1,200,000.0	$1,950,000.0	$3,680,000.0	$5,940,000.0
%SG&A	*0.0%*	*0.0%*	*57.1%*	*34.2%*	*28.8%*	*25.9%*
R&D	$500,000.0	$1,500,000.0	$1,000,000.0	$1,000,000.0	$1,000,000.0	$1,000,000.0
% R&D						
Operating Income	($850,000.0)	($2,350,000.0)	($1,200,000.0)	($200,000.0)	$1,520,000.0	$4,210,000.0
Operating Margin						
Total Other Expense (Income) - Stock based compensation	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($850,000.0)	($2,350,000.0)	($1,200,000.0)	($200,000.0)	$1,520,000.0	$4,210,000.0
Taxes (benefit)	$0.0	$0.0	$0.0	$0.0	$532,000.0	$1,473,500.0
Tax Rate	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income	($850,000.0)	($2,350,000.0)	($1,200,000.0)	($200,000.0)	$988,000.0	$2,736,500.0
Net Margin						
EPS	($0.02)	($0.04)	($0.02)	($0.002)	$0.01	$0.03
YOY Growth						
Diluted Shares O/S	43,166,667	62,750,000	72,750,000	82,750,000	92,750,000	102,750,000

Anita Dushyanth

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LEADERSHIP

Wayne Maddever, Ph.D., P.Eng.
Director, President & CEO
Wayne Maddever received his B.A.Sc./M.A.Sc/Ph.D. in Metallurgical and Materials Science Engineering from the University of Toronto. He began his career with the Gas Products Division of Union Carbide (now Praxair) in both the US and Canada where he held positions in research and development, product management and sales management. He has considerable experience in the plastic moulding industry having headed a Division of St. Lawrence Starch, which developed and commercialized degradable plastics. He is familiar with precision equipment manufacture having served as General Manager of Sanden Machine, a printing press manufacturer and as COO of CFN Precision, a precision machining company producing parts for aircraft and scientific instruments. Dr. Maddever also operated Ontario's third largest home oxygen therapy and medical supply company as General Manager-Canada for MG Industries a German industrial gases company. Since 2000 he has specialized in management of technically based companies where he has held senior management positions at a number of technically based private and publicly held companies, particularly in early stage or turnaround situations.

Dr. Maddever holds several patents and is the author of numerous technical papers in several different fields and is co-author of a textbook on degradable plastics.

James Samsoondar, Ph.D., FCACB
Director & Chief Science Officer
James Samsoondar holds a Ph.D. in Clinical Biochemistry from the University of Toronto. He completed a 2-year residence in Clinical Biochemistry to become a Certified Clinical Biochemist and subsequently a Fellow of the Canadian Academy of Clinical Biochemistry (FCACB). He is currently Chair of the Professional Affairs Committee of the Ontario Society of Clinical Chemists and a Scientific Committee member of the Quality Management Program-Laboratory Services (division of the Ontario Medical Association). Currently he is also Clinical Biochemist, Quality Manager and Chair of the Point-of-Care Testing (POCT) Advisory Committee at The Scarborough Hospital.
James has been awarded 34 patents to date and is the principal inventor in 29 patents. He developed and licensed technology to Johnson & Johnson which is incorporated into the company's Central Laboratory Chemistry Analyzer–the most utilized lab analyzer in Ontario. He developed the HemoNIR hand-held analyzer with a previous company and went on to found ChroMedX in 2005.

Chris Hopkins, C.P.A., C.A.
Chief Financial Officer
Chris Hopkins has 25 years of experience in leadership, strategic planning, mergers & acquisitions, valuations, corporate finance, investor relations, financial management, economic evaluation, systems design/implementation, and financial &management reporting, performance evaluation KPI's.
The majority of his career has been spent in senior positions with numerous publicly-listed mining companies, including U.S. Silver, Rio Algom Limited, BHP Billiton, Suncor Inc. and several Canadian and international junior mining companies.
Chris received his Bachelor of Commerce degree from the University of Toronto, his Chartered Accountant designation and his Master of Business Administration from the Schulich School of Business at York University.

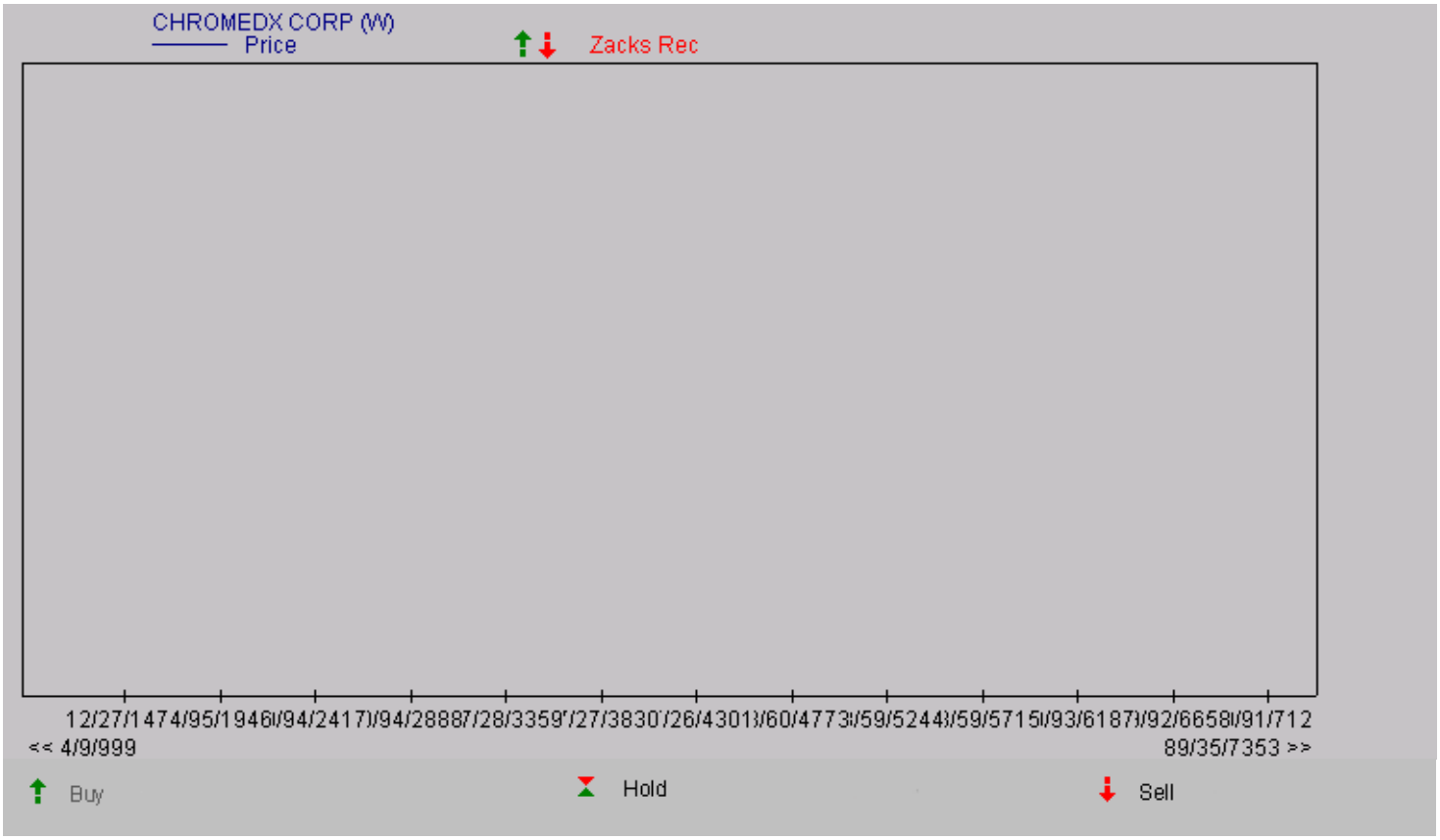
Board of Directors
George Langdon, Ph.D.,
Director
George Langdon studied geology at the Memorial University of Newfoundland, where he took BSc., MSc and PhD degrees between 1978 and 1996. He joined the petroleum industry as an exploration geologist in 1980, and worked for majors Hudson's Bay Oil and Gas in Calgary, Saudi ARAMCO in Dhahran, Saudi Arabia, and Mobil Oil Canada in Toronto, until 1999. Since that time he has acted as a consultant for, and has been involved in the development of junior public companies in the oil and gas sector, especially in eastern Canada, including Canadian Imperial Venture Corp. (TSXV-CQV) in western Newfoundland, and Contact Exploration Inc. in New Brunswick. In 2006 he became the founding President of Shoal Point Energy Ltd. (CNSX-SHP) where he served until June 2013. Dr. Langdon was co-responsible as President and lead geologist for the company's amassing a land position of some 720,000 acres in which it owns a 100% interest, and for negotiating a joint venture which aims to see up to 10 wells drilled over the next 3 to 4 years to assess this massive play, which has the potential to impact the energy balance in eastern North America over the next several years. George also received a Bachelor of Fine Arts in Music Composition from York University, Toronto, in 1990, and continues a serious interest in music.

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Michael Minder
Director
Michael Minder is a seasoned finance professional with over 15 years of international banking experience. He held senior leadership roles in Asset and Wealth Management for Credit Suisse Group in both Switzerland and North America, managing assets of high net worth accounts.
In 1998 he left the Credit Suisse Group to form his own firm providing international investment banking and investor relations advisory services to numerous U.S., Canadian, and European listed companies. Michael is the current CFO of TSX Venture listed Zecotek Photonics Inc. a Company focused on the innovation and commercialization of key enabling technology, subsystems, and components for medical and industrial imaging.

Gerard Edwards, B.Comm., MBA
Director
Mr. Edwards has a background in finance and administration and was Co-founder and past President of Imperial Venture Corp./Canadian Imperial Venture Corp., as well as a co-founder and past president of Guigne Technologies Ltd., a St. John's based high-tech company.

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