

IMI INTERNATIONAL MEDICAL INNOVATIONS INC.

ANNUAL INFORMATION FORM

In respect of the year ended

December 31, 2003



International
Medical
Innovations Inc.

May 17, 2004

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Documents Incorporated by Reference:

Attached to this Annual Information Form are the following documents:

- (a) IMI International Medical Innovations Inc.'s Annual Report for the year ended December 31, 2003 (the "Annual Report") which includes Management's Discussion and Analysis (the "MD&A"); and
- (b) IMI International Medical Innovations Inc.'s management information circular (the "Management Information Circular") dated May 10, 2004 prepared in connection with the Annual and Special Meeting of Shareholders to be held on June 16, 2004.

The MD&A, in its entirety, is incorporated by reference in, and forms part of, this Annual Information Form. Specific portions of the Annual Report and the Management Information Circular are incorporated by express reference in, and form part of, this Annual Information Form. Those portions of the Annual Report and Management Information Circular not so incorporated by express reference do not form part of this Annual Information Form.

Comments Regarding Figures Contained in this Annual Information Form

In this Annual Information Form, all references to "\$" or "dollars" are references to Canadian dollars unless otherwise specified.

Interpretation

Where used herein, the "Corporation" refers to IMI International Medical Innovations Inc., together with its subsidiary, as the context requires.

Trade-marks

Cholesterol 1,2,3TM, ColorectAlertTM, LungAlertTM and ColoPathTM are registered trade-marks of the Corporation. All other trade-marks or service marks appearing in this Annual Information Form are the trade-marks or service marks of the companies that own them.

GLOSSARY OF TERMS

The terms set forth below have the meanings set out opposite them for the purpose of this Annual Information Form.

Term	Meaning
Angiogram	Viewing of a blood vessel after filling with a contrast medium
Arteriosclerosis	Diseases characterized by thickening and loss of elasticity of the arterial walls
Atherosclerosis	Atherosclerosis, which is one of several types of arteriosclerosis, is a condition in which fatty material is deposited along the walls of arteries. This fatty material thickens, hardens and may eventually block the arteries.
CAD	Coronary artery disease, which is a narrowing of the small blood vessels that supply blood and oxygen to the heart
CAT	Computerized axial tomography - body section radiography done by moving an x-ray tube through an arc, showing in detail a pre-determined plane of tissue while blurring details of other planes
CBE	Clinical breast exam
CE-marked	A compliance symbol indicating that a product meets the requirements of the European Union (EU) directives that apply to that product. CE stands for Conformité Européenne, which means European Conformity.
CEA	Carcinoembryonic antigen - a tumor marker that is indicative of the presence of colorectal and other cancers
CHD	Coronary heart disease, another term for CAD
CVD	Cardiovascular disease, which includes all diseases of the circulatory system, including CAD/CHD, heart failure and diseases of the arteries.
DCBE	Double contrast barium enema
DRE	Digital rectal exam
Duke's Classification Method	A standard classification method for colon and rectal cancer
FDA	United States Food and Drug Administration - the federal government agency that regulates the production, safety and efficacy of biological and pharmaceutical products, diagnostics and medical devices.
FOBT	Fecal occult blood testing
GMP	Good manufacturing practice
HDL	High-density lipoprotein
HMO	Health maintenance organization
HPB	Canadian Health Protection Branch - the agency of Health Canada that regulates the production, safety and efficacy of biological and pharmaceutical products, diagnostics and medical devices in Canada
Hyperlipoproteinemia	An excess of lipoproteins in the blood
IDC	Infiltrating ductal carcinoma
IDE	Investigational device exemption

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Term	Meaning
in-license	Acquiring the rights to a technology and the related know-how from an unrelated company or institution in order to further develop, commercialize or otherwise exploit the technology
LDL	Low-density lipoprotein
Lipids	A group of organic substances, including fatty acids, which are insoluble in water
MRI	Magnetic resonance imaging
NIH	United States Department of Health and Human Services - National Institutes of Health
NSCLC	Non-small cell lung carcinoma
NSR	Non-significant risk
out-license	Granting the rights to a technology and the related know-how to an unrelated company or institution in order to further develop, commercialize or otherwise exploit the technology
PMA	Pre-marketing approval
SCLC	Small cell lung carcinoma
Sterol	A family of fat-like compounds that include cholesterol
TC	Total cholesterol
VLDL	Very low-density lipoprotein

CORPORATE STRUCTURE

IMI International Medical Innovations Inc. (the “Corporation”) was originally incorporated under the *Canada Business Corporations Act* on November 9, 1992. The Corporation was amalgamated with its wholly-owned subsidiary 2860601 Canada Inc. pursuant to the *Canada Business Corporations Act* on February 1, 1999. The only material subsidiary of the Corporation is its wholly-owned subsidiary, IMI International Medical Innovations Inc. (Switzerland), a corporation incorporated under the laws of Switzerland. The Corporation’s head office and principal place of business is located at 4211 Yonge Street, Suite 615, Toronto, Ontario, M2P 2A9. The Corporation currently rents approximately 3,500 square feet of office space at this location and occupies laboratory facilities at McMaster University in Hamilton, Ontario.

GENERAL DEVELOPMENT OF THE BUSINESS OF THE CORPORATION

Overview

The Corporation is a medical device company that licenses and manages the development and commercialization of innovative predictive medicine technologies useful in a variety of medical disorders. The Corporation focuses its efforts on medical conditions where there is a well-defined need for tests to detect serious or life-threatening diseases, particularly cardiovascular disease and cancer, which the Corporation believes it can successfully develop and bring to market. By focusing on identifying better predictors of disease as well as simpler screening methods, IMI aims to detect people’s risk of diseases at the earliest possible stage when they can be more effectively treated, or perhaps prevented altogether.

The Corporation seeks out proprietary technologies that offer some evidence of efficacy in human trials and significant cost/benefit trade-offs to existing products. The Corporation evaluates each technology, including intellectual property assessments, and conducts competition and market research in order to select those technologies or products that have the greatest potential. In effect, the Corporation invests substantially all of its funds in product development (as opposed to basic research) and clinical trials. By investing in this phase of development, management of the Corporation believes that it can add value for its shareholders and avoid the more expensive and riskier research stage of the product development cycle.

After identifying and evaluating an appropriate technology, the Corporation purchases or in-licenses the related patents or know-how, completes the development of prototypes and defines the manufacturing protocols. Where appropriate, the Corporation conducts clinical trials to obtain regulatory approval and register the product for sale. At a point in the development cycle for the technology, the Corporation seeks to out-license its products to major diagnostic, pharmaceutical or consumer goods companies, which could be responsible for any or all of the related marketing, sales, manufacturing and distribution. The Corporation intends to negotiate to receive research and development support, upfront and milestone payments and an on-going royalty interest on the sales of these products.

The Corporation currently owns patents for coronary artery disease (CAD) risk assessment technology, which is used to measure skin cholesterol for determining an individual’s risk of CAD, and has in-licensed the technologies for tests to detect the presence of a marker intended for use in colorectal, lung and other cancers. In addition, the Corporation has patents pending for colour measurement in biological reactions and has a right of first refusal on certain related technologies in the predictive medicine field on

research being conducted at McMaster University. The Corporation has also acquired the exclusive rights to a hand-held instrument and software for colour measurement for use with skin cholesterol testing in point-of-care applications. The Corporation believes that these innovative technologies will fulfil market needs through their ease-of-use and by contributing to cost-effective patient management.

To acquire these technologies, the Corporation has negotiated agreements with the inventors of the technologies with the objective of building long-term relationships and mutual cooperation. To date, the Corporation has acquired technology rights through a combination of equity participation by the inventors, profit sharing, royalties, up-front payments and commitments for funding ongoing product development expenses. As well, all scientific discoveries made during the course of a product's development become property of the Corporation. This has led to several new patent applications.

In October 2003, the Corporation received ISO 13488:1996 Quality System Certification from a Canadian Medical Device Conformity Assessment System (CMDCAS)-recognized registrar. This certification, which is now a regulatory requirement in Canada and Europe for new product license submissions, confirms that the Corporation meets the highest international standards for quality control and customer service.

Product Pipeline

The Corporation's current pipeline of products targets four of the body's vital components --- the heart, colon, lungs and breasts:

- Coronary Artery Disease (CAD) Risk Assessment Technology*
 - Cholesterol 1,2,3TM (cleared for sale in Canada, U.S.(CLIA-exempt) and Europe)
 - Lab-processed test (patent-pending)
 - Home test (in development)
- ColorectAlertTM
- LungAlertTM
- Breast cancer test

**In November 2003, the Corporation announced that its skin cholesterol test will be branded in Canada on behalf of the Corporation by McNeil Consumer Healthcare as PREVU* Coronary Heart Disease Predictor ("PREVU*")*

Business Strategy

Identify and Target Significant Markets with Unmet Needs

The Corporation focuses its efforts on medical conditions where there is a well-defined global need and demand for tests to detect serious or life-threatening diseases, which the Corporation believes it can successfully develop and bring to market. The Corporation's products address cardiovascular disease ("CVD") and cancer, diseases where early detection, intervention and ongoing monitoring can significantly improve patient outcomes. CVD claims the lives of 17 million people worldwide each year, and has no geographic, gender or socio-economic boundaries (*World Health Organization World Health Report, 2003*). Colorectal, lung and breast cancers combined kill approximately two million people annually worldwide (*Globocan 2000, Cancer Incidence, Mortality and Prevalence Worldwide - International Association for Cancer Research/World Health Organization*).

Ensure a Multiple Product Pipeline

The Corporation pursues sustained development by building and maintaining a portfolio of products at different stages, which helps to mitigate risk while enhancing opportunities to generate value for stakeholders. The Corporation continuously assesses and studies other possible applications of its technologies. In addition, the Corporation continues to seek out and evaluate new, proprietary technologies that have undergone initial proof-of-principle tests and that offer clear cost/benefit trade-offs to products currently available.

Pursue Strategic Relationships

The Corporation pursues a strategy of building collaborative relationships with leading companies to conduct clinical trials and to assist with the development of its products. The Corporation also seeks, at the appropriate time, to out-license its products to major diagnostic, pharmaceutical or consumer goods companies, which could be responsible for any or all of the related marketing, sales, manufacturing and distribution. This strategy allows the Corporation to minimize the expenses and risks of large-scale product development and commercialization while helping to reduce time to market. In addition, through these relationships, the Corporation gains the benefit of others' expertise, which enhances the ability of the Corporation to pursue multiple product opportunities.

Establish and Maintain Strong Intellectual Property Portfolio

Patents and other proprietary rights are essential to the Corporation's business. The Corporation files patent applications to protect technology, inventions and improvements to technology or inventions that are considered important. Such applications may cover composition of matter, the production of active ingredients and their novel applications. The Corporation has acquired, by licence or assignment, rights to patents and applications filed in Canada, the U.S. and internationally. The Corporation also relies upon trade secrets, non-patented proprietary know-how and continuing technological innovation to develop and maintain its competitive position.

Leverage Management's Scientific, Product Development and Commercialization Expertise

The Corporation is led by an experienced group of individuals with significant industry expertise in the areas of research, regulatory affairs, new product launches, sales and marketing, and finance.

BUSINESS OF THE CORPORATION

Industry Overview

The Market for Diagnostics

According to the United States Census Bureau, the U.S. population aged 65 and older is projected to double over the next three decades from an estimated 35.3 million in 2003. The Census Bureau projects that the 65-plus population will number 39.7 million people in 2010, 53.7 million in 2020 and 70.3 million, or 20% of the U.S. population, in 2030. The number of Americans above the age of 65 in 1940 was approximately 8.9 million.

The aging population has caused a dramatic growth in total health care spending. As a result of these increasing expenditures, cost containment strategies are being evaluated and implemented by

governments and private payers around the world. Management believes that technologies that help to detect disease early and help reduce health care costs, especially if quality of care is not adversely impacted, should represent a significant market opportunity. Health care cost containment efforts are also shifting treatment focus away from hospitals to less expensive alternative care sites.

Technological advances have created more effective, easy-to-use devices that have allowed risk assessment to be moved closer to the patient. This has resulted in the earlier identification and the initiation of therapy or prevention at an earlier stage in the healthcare process. Management believes that point-of-care or self-testing is optimal because it permits immediate feedback to the patient or medical practitioner, rather than requiring additional and delayed patient contact to provide and explain results. It also reduces the need for costly return visits to the doctor and avoids the expense of specimen collection, preservation, transportation, processing and results reporting by laboratories. In some cases, hospitals, health maintenance organizations (“HMOs”), health departments and corporations view screening as an effective way to reduce overall medical costs. As a result, the use of screening and monitoring diagnostics for early intervention, improved treatment and monitoring is becoming an important component of managed health care. This trend toward greater use of point-of-care and self-diagnosis began in the early 1980s and is expected to continue. Examples of such tests include those for cholesterol, glucose, pregnancy, ovulation and various urine components. Management believes that the factors discussed above will lead to increases in the use of devices of the type that the Corporation currently intends to commercialize.

Several large companies, including Abbott Laboratories Limited, Bayer Inc., Beckman Coulter Inc., Becton Dickinson, Johnson & Johnson and Roche Diagnostics Systems, dominate the medical device and diagnostics industry. Relative to the pharmaceutical industry, product development is generally characterized by lower development costs, shorter regulatory timelines and a shorter time to market. These advantages may be offset by somewhat lower margins as compared to the pharmaceutical industry.

The Point-of-Care Market

Theta Reports estimates that in 2000 the worldwide market for total point-of-care tests performed in a professional setting was almost US\$2.3 billion. In 2005, Theta projects that this market will increase to approximately US\$3.8 billion. Approximately 50% of these point-of-care tests are sold in North America and approximately 25% are sold in Western Europe.

The Home Testing Market

Complementing the trend towards increased use of point-of-care diagnostics is the expanding market for self-testing and home-use diagnostic tools which are generally available at pharmacies as over-the-counter products. The growth of this market has been attributed to the following four main factors:

1. greater awareness of personal wellness and the increasing role by individuals in health maintenance;
2. a health-conscious and aging population which is placing a growing emphasis on preventative care;
3. technological advances that have improved both the ease-of-use and accuracy of diagnostic products, thereby gaining greater support from medical practitioners; and
4. availability of over-the-counter (“OTC”) products and other therapies to treat serious diseases.

According to Frost & Sullivan, an international market research and consulting firm headquartered in Mountain View, California, the combination of preventative awareness, healthcare reform and managed care has had a positive impact on the home diagnostics and monitoring products market. Frost & Sullivan expects that these new emerging diagnostic and monitoring trends will likely help to detect disease early, thereby speeding patient recovery and reducing long-term medical expenses. In the U.S., revenues from home diagnostic products and monitoring devices grew at a rate of 11.9% compounded annually from US\$1.19 billion in 1994 to US\$1.70 billion in 1997 (*Frost & Sullivan, 1998*).

Between 2002 and 2007, the global OTC market for home diagnostic testing is expected to increase by 49%, at a compound annual growth rate of 8.3% (*PJP Publications Ltd., 2003*). The U.S. dominates the global market for OTC diagnostic testing. In 2002, the total U.S. home testing market was valued at US\$2.65 billion (*Greystone Associates, Cholesterol Monitoring: Self-Testing Markets and Opportunities, 2003*).

Channels of Distribution

Until recently, most complex diagnostic procedures were performed in hospitals with in-house laboratories and in centralized clinical laboratories. As a result, sales and distribution efforts by manufacturers of diagnostic products have focused on such laboratories. This market has been, and continues to be, serviced almost entirely by large, integrated marketing and distribution companies. These large companies maintain strong sales and marketing departments including salespeople calling directly on physicians' offices. However, technological advances resulting in new and/or improved product offerings are changing the market. This product innovation has allowed for expanded use of complex diagnostic products in doctors' offices, corporate health centres and the home. The result is a greatly expanded set of potential markets with a similarly expanded set of distribution channels.

Management of the Corporation anticipates that several of the Corporation's products will extend into these new market segments. With its initial products, the Corporation anticipates establishing strategic alliances with pharmaceutical, diagnostic or consumer goods companies. Such companies would ideally offer conventional distribution networks supplemented by direct selling to select markets such as work sites, community health centres, preventive care facilities or home care networks.

On May 10, 2002, the Corporation entered into an agreement with McNeil Consumer Healthcare, a Johnson & Johnson company, for the marketing and distribution of the Corporation's skin cholesterol tests for coronary artery disease in Canada. This agreement was amended on December 20, 2002 to include the laboratory field and to extend the territory for the insurance testing market to include the U.S. and Mexico.

In November 2003, the Corporation announced that its skin cholesterol test will be branded in Canada by McNeil Consumer Healthcare as PREVU* Coronary Heart Disease Predictor ("PREVU*").

Coronary Artery Disease (CAD) Risk Assessment Technology

Skin Cholesterol Pathology

Cholesterol is transported in the blood by plasma lipoproteins. Four major lipoprotein classes can be identified on the basis of their physiochemical properties: chylomicrons, very low-density lipoproteins ("VLDL"), low density lipoproteins ("LDL") and high-density lipoproteins ("HDL").

The deposit of cholesterol onto damaged blood vessel walls results in the development of a lesion that eventually reduces both the flexibility of the afflicted blood vessel wall and the intravascular space. The resultant condition is known as an atherosclerotic plaque.

LDL fractions contain 75% of the blood cholesterol and are associated with deposits on artery walls. In contrast, HDL fractions bind to some of the cholesterol in blood and transport it to the liver where it is metabolized. Thus, in general, elevated LDL, in the absence of elevated HDL, is associated with atherosclerosis whereas elevated levels of HDL, alone are associated with lower levels of disease.

Lipoprotein concentrations in the blood can change as a result of normal physiological variation, which averages about 6.1% (United States General Accounting Office: Report to the Chairman, Submitter on Investigations and Oversight, Committee on Science, Space and Technology, House of Representatives; Cholesterol Measurement - Test Accuracy and Factors that Influence Cholesterol Levels, 1994). In order to establish accurate levels, measurements are made using several blood samples taken at varying intervals after fasting. Self-administered tests can also be done using finger stick blood samples and these can be even more variable than measurements in venous samples. Although the United States National Cholesterol Education Program ATP III (the "NCEP") experts' panel (NCEP Report of the Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults, (Adult Treatment Panel III) 2001) recommends that all Americans over the age of 20 have their blood cholesterol measured at least once every five years, standard tests may not adequately predict the risk of cardiovascular disease.

Atherosclerotic plaque results in increased risk for:

- ? coronary artery disease ("CAD"), angina pectoris and sudden cardiac death
- ? stroke
- ? peripheral vascular disease

Market

High cholesterol and other lipid disorders are among the world's most widespread chronic health problems. In response to conclusive evidence relating high cholesterol to heart disease, the NCEP was launched by the United States National Institutes of Health (the "NIH") in 1985 as part of a U.S. nationwide effort to reduce the prevalence of high blood cholesterol. The NIH recommends that the least expensive way to reduce CHD is through a public health approach that targets the entire population to reduce the major risk factors for heart disease, including cholesterol from dietary intake. Most Americans are now aware that high cholesterol levels increase their risk of having heart disease.

In 1988, the NIH issued guidelines for the screening of all adults over 20 years of age to determine total cholesterol ("TC") levels and proposed more extensive lipid testing and treatment for those found to have high TC. In 1991, screening guidelines were expanded to include children over the age of two with a family history of high TC or CHD.

NIH guidelines provide that individuals with satisfactory TC values should have their cholesterol tested every five years, individuals with borderline high TC should have a lipid testing repeated annually, and those with high TC should have at least three lipoprotein tests conducted to confirm their values and to help their physician decide what therapy, if any, should be instituted. Individuals receiving diet or drug therapy may be re-tested every three to six months to track the effectiveness of the therapy.

Since the inception of the NCEP, the market for cholesterol and other risk assessment tests has experienced significant growth. A study in the "Morbidity and Mortality Weekly Review", United States Center for Disease Control, September, 2000, reported that the percentage of Americans who have had their cholesterol checked jumped from 67% in 1991 to 71% in 1999. According to a 2004 report by the American Heart Association, in 2001, approximately 104 million Americans adults, representing approximately half the U.S. adult population, had elevated cholesterol levels and more than 37 million American adults had cholesterol readings over the danger level. Clinical laboratories in the U.S. now perform approximately 250 million cholesterol tests per year and another 290 million clinical laboratory tests are performed in the rest of the world.

The economic impact of cardiovascular disease on the U.S. health care system is growing larger as the population ages. In 2003, the total cost of heart disease and stroke was estimated at US\$351 billion: US\$209 billion for health care expenditures and US\$142 billion for lost productivity from death and disability (*National Center for Chronic Disease Prevention and Health Promotion*). The total cost of heart disease and stroke in 2004 is projected to reach US\$368 billion.

The Opportunity

Management of the Corporation believes that there is a need for a more reliable, patient-friendly and cost effective means of assessing as well as monitoring patients. Blood cholesterol tests may be highly variable in results over a series of days, relatively expensive to perform and require a blood sample from the patient. In response to this opportunity, in 1993 the Corporation acquired the patent rights underlying the Corporation's skin cholesterol technology for the U.S., Canada and Western Europe and later expanded its intellectual property rights covering such technology. See "Business of the Corporation - Coronary Artery Disease (CAD) Risk Assessment Technology - Patents".

The Technology

Since the mid-1960s, scientists have tried to measure skin cholesterol as a marker for cardiovascular disease, recognizing it had the potential to provide additional information about CVD risk over blood cholesterol testing. Skin contains over 11% of the body's cholesterol and ages in parallel with vascular connective tissue. Thus, as blood vessel walls accumulate cholesterol, it is believed that skin accumulates cholesterol. This has led to the hypothesis that skin may be a better source of estimating CAD than blood. A number of studies carried out in the 1970s and early 1980s, largely in Europe, have provided evidence in support of this hypothesis. The results of these studies indicate that:

- ? skin cholesterol levels were found to be higher in individuals with abnormal coronary angiograms than in those with normal coronary angiograms;
- ? skin cholesterol levels were found to be elevated in individuals with hyperlipoproteinemia compared to those with normal serum lipid levels; and
- ? skin cholesterol levels were elevated in individuals having coronary bypass surgery compared to age-matched healthy controls.

In most of the prior studies, skin cholesterol was estimated after extraction from tissue sample using organic solvents. Thus the nature of the sample precluded its use in general clinical practice.

The Corporation's Cardiovascular Products

Cholesterol 1,2,3 is a non-invasive test that evaluates the amount of cholesterol accumulated in a patient's epidermis (skin) surface. The test is conducted in three minutes in two separate steps on the palm of the hand. In the first step, a chemical solution consisting of a cholesterol-binding agent and an enzyme, linked together by a synthetic copolymer, is placed on the hand for one minute. This solution binds to the skin's cholesterol-rich surface layer. After one minute the excess solution is blotted dry, leaving only that part of the solution that is bound to epidermal cholesterol. In the second step, an indicator solution, containing a dye in a colourless form, is placed on the same area of the hand and reacts when it contacts the enzyme, which is bound to epidermal cholesterol. As a result, a colour change reaction is created. After only two minutes, a hand-held colour measurement instrument reads this reaction and produces a numerical result.

Cholesterol 1,2,3 is packaged in a 20-test kit that contains three dropper bottles consisting of a binding solution, an indicator solution and a positive control, as well as 20 adhesive-backed pads. In addition, a patented hand-held instrument (see "Coronary Artery Disease Risk Assessment Technology - Development History and Clinical Findings"), which connects to a computer is used to measure the colour change and provides a skin cholesterol value. The results of this test give an indication of the patient's CHD risk.

Cholesterol 1,2,3 has a shelf life of 15 months. Management of the Corporation believes that this test is inexpensive to produce and will be cost competitive with current alternative tests. Cholesterol 1,2,3 could be used in physicians' offices, laboratories, clinics and pharmacies.

To help ensure the broad market appeal and long-term commercial success of the Corporation's cardiovascular franchise, the Corporation is adapting its technology for two new formats:

- A lab-processed test, which is administered painlessly and rapidly at the point-of-care, without fasting, needles or blood sample required. The testing procedure samples surface skin cells from the palm of the hand using a specially designed device with medical-grade adhesive, which is then sent to a laboratory where the surface is assessed for skin cholesterol. This test, which is patent -pending, is nearing the production stage.
- A single-use, two-minute test designed primarily for home use, is also currently in development.

Development History and Clinical Findings

Validation of the synthesis of the chemicals comprising the binding solution of Cholesterol 1,2,3 was conducted at McMaster University, Hamilton, Ontario ("McMaster"), pursuant to a research service agreement executed in April 1997, as amended in October 2000, between McMaster and the Corporation. The Corporation provides research and development sponsorship funding to McMaster, which funding commenced in November 2000 and will continue until October 31, 2005. In consideration for this sponsorship, the Corporation has a right of first refusal for a license on any intellectual property that is created as a result of the funding. The Corporation also has the right under this agreement for the use of laboratory facilities at McMaster.

From November 1997 to December 1998, the Corporation conducted a clinical trial at The Cleveland Clinic Foundation (the "Cleveland Clinic"), Preventive Cardiology and Rehabilitation Section, with Dr.

Dennis Sprecher as principal investigator. The main objective of this primary study was to evaluate Cholesterol 1,2,3's ability to assess the risk that a person has cardiovascular disease by:

1. determining the relationship between skin cholesterol and serum lipid levels in 200 patients entering the preventive cardiology program; and
2. determining the relationship between skin cholesterol and functional evidence of CAD as demonstrated by cardiac stress testing and trans-esophageal echocardiography ("TEE") in the test population (100 patients each).

The results of the study were presented at the 31st Annual Oak Ridge Conference in San Jose, California on April 23, 1999. The data showed that skin cholesterol was an independent predictor of functional cardiovascular disease (as measured by stress test outcome).

On May 14, 1999, the Corporation entered into a supply agreement (the "X-Rite Agreement") with X-Rite, Inc. ("X-Rite"), a Michigan based corporation, under which X-Rite agreed to develop and supply the Corporation with a hand-held instrument (the "X-Rite Instrument") and related software for skin cholesterol testing in a professional setting. The X-Rite Instrument measures the colour of the reagents on the palm of the hand and provides a quantitative skin cholesterol result.

Pursuant to the terms of the X-Rite Agreement, the Corporation has agreed to purchase all of the Corporation's worldwide requirements for colour measuring devices and related software for use by the Corporation in marketing and selling Cholesterol 1,2,3 Systems (defined in the agreement as the product or system combining the use of Cholesterol 1,2,3 and the X-Rite Instrument) in point-of-care applications applied under the direction or supervision of medical practitioners and clinicians. The term of the X-Rite Agreement is six years unless earlier terminated by either party upon the material breach by the other party or, at the option of X-Rite, if a certain minimum number of Cholesterol 1,2,3 Systems are not purchased. Further, under specific conditions, the Corporation may be required to make certain payments to X-Rite if less than a minimum number of X-Rite Instruments have been purchased by the Corporation during a specified period following FDA approval of Cholesterol 1,2,3. Other than for purchases of X-Rite Instruments in the ordinary course of business, the Corporation has not paid X-Rite any amounts under the X-Rite Agreement to date.

A second study, conducted at the Cleveland Clinic, was designed to determine the ability of Cholesterol 1,2,3 to serially monitor 50 patients starting lipid-lowering medications and to test each patient's ability to self-test. The interim results of this study were presented at the annual meeting of The American Association of Clinical Chemistry ("AACC") in New Orleans on July 27, 1999. This data suggested that non-invasive determination of skin cholesterol levels might have utility in monitoring response to cholesterol-lowering medications.

A follow-on clinical study to determine the effectiveness of measuring skin cholesterol levels to assess CAD was undertaken at The Canadian Heart Research Centre, The Trillium Health Centre and the Cleveland Clinic, with Dr. Dennis Sprecher acting as the principal investigator. The study measured skin cholesterol levels in 649 patients with the resulting values being compared to angiography. Interim results were presented at the American Heart Association's ("AHA") Scientific Sessions, New Orleans in November 2000. Further results were presented at the AHA's Arteriosclerosis, Thrombosis, and Vascular Biology Meeting, in Salt Lake City, in April 2002. The study demonstrated that skin cholesterol was independently associated with the presence and extent of CAD as determined by angiography, the gold standard for diagnosis of CAD.

In addition, a clinical trial was completed in April 2001 at St. Paul's Hospital at the University of British Columbia, Vancouver, British Columbia, comparing skin cholesterol measurements to other measures of CAD risk, including carotid sonography, flow-mediated brachial vasoactivity, and serum markers from this trial, published in the June 2002 issue of the American Journal of Cardiology. The results showed that skin cholesterol was correlated with Framingham global risk and inflammatory markers, notably ICAM-1.

In March 2002, Cholesterol 1,2,3 was added to the Johns Hopkins site of the Multi-Ethnic Study of Atherosclerosis ("MESA"), a 6,500 patient multi-site clinical trial. The eight-year prospective MESA trial will examine a variety of methods, including skin cholesterol, for identifying sub-clinical disease (disease with no overt symptoms) in a diverse patient population of Caucasians, African Americans, Hispanics and Asians. Initial study findings were presented at the American Heart Association 2003 annual meeting. In the skin cholesterol study cohort, 222 adults with no known cardiovascular disease were tested. Skin cholesterol levels correlated with the presence and extent of coronary artery calcification, a risk marker for CAD.

In August 2003, Cholesterol 1,2,3, was added to AtheroGenics, Inc.'s Aggressive Reduction of Inflammation Stops Events ("ARISE") multi-site phase III trial, being conducted at up to 180 sites in the U.S., Canada, United Kingdom and South Africa. The collected data will quantify the relationship between skin cholesterol and primary cardiovascular events (e.g., heart attacks, strokes), AtheroGenics' AGI-1067 drug, and other risk factors, including serum lipids and patient demographics. The trial will provide valuable primary-event data and broad exposure of Cholesterol 1,2,3 to leading cardiologists and cardiac centers around the world.

In addition to the Cholesterol 1,2,3 product, the Corporation is advancing development of laboratory-processed and consumer formats of the skin cholesterol test and has commenced pilot studies on prototype tests.

The following table summarizes the development and clinical evaluations of the Corporation's skin cholesterol test to date:

Stage of Development	<ul style="list-style-type: none"> • Professional test approved for sale in U.S., Canada, Europe • Lab-processed test in clinical trials • Consumer (home) test in development
Key Completed Studies	<ol style="list-style-type: none"> 1. Stress test study <ul style="list-style-type: none"> • Skin cholesterol values correlated with result of coronary stress test 2. Angiography study <ul style="list-style-type: none"> • Skin cholesterol values correlate with presence and extent of CAD • Skin cholesterol is a new, independent risk factor for CAD that provides new information about CVD 3. Inflammatory markers study <ul style="list-style-type: none"> • Skin cholesterol correlates with inflammatory markers for CAD, including ICAM-1 • Skin cholesterol correlates with Framingham global risk score 4. Response to therapy study (The Cleveland Clinic Foundation) <ul style="list-style-type: none"> • Skin cholesterol changes may have value in monitoring response to cholesterol-lowering drug therapy 5. Pediatric skin cholesterol study (St. Joseph's Healthcare) <ul style="list-style-type: none"> • Skin cholesterol can be reliably measured in children 6. MESA (Multi-Ethnic Study of Atherosclerosis) (National Heart, Lung and Blood Institute U.S.) <ul style="list-style-type: none"> • Skin cholesterol correlates with presence of coronary artery calcification • Skin cholesterol can provide useful index of subclinical (hidden) cardiovascular disease
Current/Planned Studies	<ol style="list-style-type: none"> 1. ARISE (Aggressive Reduction of Inflammation Stops Events) (AtheroGenics, Inc.) <ul style="list-style-type: none"> • Being conducted at up to 180 cardiac centers in Canada, U.S., U.K. and South Africa 2. Framingham study (The Cleveland Clinic Foundation) <ul style="list-style-type: none"> • To acquire additional data relative to Framingham global risk score 3. Statin compliance (The Cleveland Clinic Foundation) <ul style="list-style-type: none"> • Determine whether skin cholesterol can be used to measure compliance with therapy 4. WAVE (Canadian Institute for Health Research) <ul style="list-style-type: none"> • Determine skin cholesterol correlations with significant cardiac events in high-risk patients 5. Carotid IMT and skin cholesterol levels (University of Wisconsin) <ul style="list-style-type: none"> • Determine if skin cholesterol will predict carotid IMT in patients without history of stroke coronary heart disease 6. Additional studies in progress

Regulatory Clearance

In January 2001, regulatory clearance was granted by the HPB for sale of Cholesterol 1,2,3 in Canada for risk assessment of coronary artery disease.

In June 2002, the Corporation received FDA clearance for sale of Cholesterol 1,2,3 in the U.S. as part of risk assessment for coronary heart disease in persons with a history of myocardial infarction and/or persons suspected of having significant multi-vessel coronary artery disease (>50% stenosis in >1 vessel as diagnosed by coronary angiography) where further diagnostic evaluation is being considered. Test results, when considered in conjunction with clinical evaluation, blood cholesterol tests and other risk factors identified for coronary artery disease, will aid the physician in focusing diagnostic and patient management options.

On September 5, 2002, the Corporation CE-marked Cholesterol 1,2,3, enabling the Corporation to sell this product in Europe as part of a risk assessment for coronary artery disease. The product was registered with the Competent Authority in the U.K. Registrations with Competent Authorities of other European Union Member States are can follow after translation of the labelling for Cholesterol 1,2,3 in their respective languages has been completed.

Marketing and Distribution

The Corporation signed an agreement with McNeil Consumer Healthcare (“McNeil”) in May 2002 (and amended in December 2002) to market and distribute the Corporation’s skin cholesterol-based cardiac risk prediction systems such as Cholesterol 1,2,3 in Canada and in the insurance testing field in the U.S. and Mexico.

The amended agreement provides McNeil with exclusive rights, in these fields and in this territory, to the present and future versions of the Corporation’s skin cholesterol tests, which are being jointly developed by McNeil and the Corporation. The agreement has a 15-year term and requires McNeil to purchase the Corporation’s skin cholesterol-based tests and pay ongoing royalties to the Corporation on sales, in addition to a series of milestone payments, which will be based on the licensed products. The Corporation may terminate this agreement if certain minimum levels of sales of the skin cholesterol test are not met. Since future royalty rates, royalties and milestone payments under this agreement are based on specific sales targets, the Corporation is unable at this time to accurately predict the aggregate future payments that could be received under this agreement.

Patents

The Corporation has obtained patents that cover the chemical formulations for the reagents employed in skin cholesterol testing as well as a method of using the same reagents for the visual indication of cholesterol on skin surface. A Canadian patent was granted in June 1995, two U.S. patents were granted in February 1996 and December 1996 and a patent covering most of Western Europe was granted in 1996. In December 1995, an international patent application was filed under the Patent Cooperation Treaty covering a multi-layer, analytical element for use in conjunction with Cholesterol 1,2,3. To date, the Corporation has received a positive response from the International Preliminary Examining Authority with respect to the patentability of such an analytical element, and, in fact, a patent was granted in both Australia and Korea in 1999. A notice of allowance was received in the U.S. in 2002.

In May 1998, the Corporation acquired the worldwide patent rights for a method for determining skin cholesterol through the use of biosensor devices. In April 2002, the Corporation was granted this patent in the U.S. It is currently pending in Europe, Canada and Japan. The Corporation has filed a patent with regards to the use of spectrophotometric measurement in colour-based biochemical and immunological assays. This patent was filed on a worldwide basis. See “Business of the Corporation - Patent and Proprietary Protection”.

In 2003, the Corporation received a new patent in the U.S. titled "Multi-layer Analytical Elements", which further protects the technology. In April 2004, the Corporation filed a patent application for its lab-processed skin cholesterol test with the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office.

Trade-marks

The Corporation filed a trademark application on February 22, 2000 with respect to Cholesterol 1,2,3 with the U.S. Patent and Trademark Office. The Corporation received the Notice of Allowance on January 31, 2003. The Cholesterol 1,2,3 trademark has been granted in Canada as well as in Europe.

Competition

The measurement of cholesterol is currently conducted through blood-based analysis. The Corporation is not aware of any other test currently marketed or in development that non-invasively measures skin cholesterol. The Corporation is aware that research has been undertaken using other testing approaches that employ body fluids, such as saliva and tears. The stage of development of such approaches is unknown. See "Risk Factors".

The cholesterol testing market can be divided into three distinct segments: (i) the point-of-care segment; (ii) the clinical laboratory setting; and (iii) the home use segment. Currently, the majority of cholesterol testing is performed in a clinical setting, which includes hospital-based and independent laboratories. These facilities employ sophisticated multi-test analyzers, which perform a wide range of blood-based diagnostic tests. These analyzers are manufactured by companies such as Beckman Coulter, Ortho Clinical Diagnostics, Roche Diagnostics Systems, Abbott Laboratories Limited and Bayer, Inc. They must be operated by skilled technicians, and, for certain tests, the pre-treatment of the blood samples is required.

In the point-of-care market, desktop analyzers have been developed, offering a more limited range of tests than clinical analyzers. These devices offer ease-of-use and immediacy of results as primary advantages over clinical analyzers, which are usually distantly located from the patient. These point-of-care tests are all invasive, requiring, at a minimum, a lancet puncture to the finger for blood to conduct the test. Some of the firms involved in the development or marketing of such products include Roche Diagnostics Systems, Lifestream Technologies, Inc. and Cholestech Corporation. Another U.S.-based company, Chematics, Inc., is marketing a point-of-care, three-minute blood-based test that is available on a mail-order basis. The Corporation believes that its skin cholesterol tests will compete effectively in the point-of-care and laboratory-testing markets based on a combination of accuracy, ease-of-use, non-invasive, immediacy of results and cost effectiveness. Management of the Corporation believes that if the results of the clinical trials confirm the results of the earlier studies, any resulting papers or presentations could play an important role in enhancing the endorsement and adoption of skin cholesterol testing by the medical community.

Key Markets

The Corporation envisions the following markets or marketing strategies for its skin cholesterol technologies:

- **Physician's office.** The non-invasive, cost effective and easy-to-use skin cholesterol test is suitable for use in the physician's office for risk assessment and, perhaps, monitoring applications providing the clinician valuable additional data in an overall patient workup for CAD risk.
- **Monitoring for drug and dietary therapy.** Given the ease of use of skin cholesterol testing, the test may be used to monitor the progress of therapy. Thus, pharmaceutical companies may be interested in using or co-marketing this test to ensure patient compliance. (The Corporation's skin cholesterol test is not yet cleared for this use.)
- **Pharmacy market.** Tests may be offered through retail pharmacies to consumers. As well, pharmaceutical companies might be interested in using or co-marketing the tests at the pharmacy level as a means of encouraging individuals to see their doctors for cholesterol lowering drug therapies. (The Corporation is currently developing this format.)
- **Screening for insurance risk assessment.** The market for insurance testing represents a significant opportunity for the Corporation's predictive heart disease test throughout North America. Millions of insurance policies are granted every year without the benefit of a cardiovascular disease assessment. In 2002, Americans purchased US\$2.9 trillion of new life insurance coverage.
- **Home testing market.** Tests could be purchased by individuals in a retail pharmacy and self-administered at home to test and monitor skin cholesterol levels. The U.S. cholesterol self-test market is projected to grow from about US\$30 million in 2003 to just under US\$150 million in 2007, driven largely by the introduction of non-invasive measurement products. (*Greystone Associates, Cholesterol Monitoring: Self-Testing Markets and Opportunities, 2003*)

Colorectal Cancer Tests (ColorectAlert and ColoPath)

Pathology

Colon and rectal cancer is the third most prevalent cancer in North America and the second most common cause of death due to cancer. Colorectal cancer begins as a benign polyp that subsequently evolves into a malignant lesion. The cancer becomes invasive when it penetrates the wall of the colon or rectum. Spread may be by lymphatics or blood vessels and occasionally along nerves. Untreated colorectal cancer leads to death.

Colon and rectal cancer is staged by imaging and biopsy studies. According to the Duke's Classification Method, colorectal cancer is categorized into four groups:

- Stage A: tumor is limited to the wall of the colon or rectum
- Stage B: tumor has extended to the extracolonic or extrarectal tissue but there is no involvement of regional lymph nodes
- Stage C: tumor has spread to regional lymph nodes
- Stage D: tumor has spread to distant organs

Early stage disease is not associated with symptoms and about 60% of all cases have spread beyond the colon or rectum (Stages C and D) at the time of diagnosis. Common symptoms associated with later stage disease include blood in the stool, abdominal pain, change in bowel habits and unexplained weight loss. Surgery is the treatment of choice for early stage disease and surgery, chemotherapy and/or radiotherapy may be used to alleviate symptoms in later stage disease. Overall, 50% of the surgically treated patients are cured with early surgical intervention.

Colorectal Cancer Screening

In the absence of effective treatment for advanced stage disease, screening is important. Screening must identify early stage disease in asymptomatic individuals in order to be effective. According to the Colorectal Cancer Association of Canada, when detected early, colorectal cancer has a 90% cure rate. Currently, there are four methods that are accepted for colorectal cancer screening:

- ? digital rectal examination (“DRE”)
- ? fecal occult blood testing (“FOBT”)
- ? sigmoidoscopy
- double contrast barium enema (“DCBE”)

DCBE every five years is now recommended by the American Cancer Society as a viable screening alternative for detection of colorectal cancer. Digital rectal examination is a simple and safe procedure but fewer than 10% of colorectal cancers can be detected by this method. Sigmoidoscopy allows for more extensive evaluation of the rectum and sigmoid colon although it has lower rate of patient acceptability and is more expensive than other methods. FOBT is the most frequently used screening method for colorectal cancer. Most national healthcare organizations in the U.S., including the American Cancer Society and the United States Preventative Services Task Force, have recommended annual fecal occult blood testing for individuals over the age of 50. Although FOBT has been found to reduce death due to eventual cancer, the test does have limitations due to its relatively low levels of sensitivity and specificity.

Market

The American Cancer Society projects that in 2004 there will be an estimated 146,940 new cases of colorectal cancer in the U.S. and more than 56,730 deaths (accounting for 10% of all cancer deaths) resulting from the disease. This relatively high mortality rate is due in part to the lack of accurate screening tests for the early detection of the disease (*American Cancer Society, Cancer Facts and Figures 2004*). The primary risk factor for colorectal cancer is age, with more than 90% of cases diagnosed in individuals over the age of 50.

On average, 13 person years of life are lost for each colorectal cancer death. In addition, treatments such as surgery, colostomies, chemotherapy and radiotherapy can also produce significant illness. Early detection of cancer is a high priority given the high cost of treatment and the costs associated with the premature death. The most prevalent test is FOBT but many patients and professionals generally do not want to perform the test because it involves smearing stool samples on a slide and because the test has relatively poor predictive values. Only 38% of colorectal cancers are discovered at an early, localized stage (*American Cancer Society*).

The Opportunity

The Corporation's rectal mucus test ("ColorectAlert") is a patented technology that detects a carbohydrate marker associated with cancerous and pre-cancerous conditions. Dr. A.K.M. Shamsuddin (the "ColorectAlert Inventor") of Baltimore, Maryland developed this technology at the University of Maryland School of Medicine. Pursuant to agreements (the "ColorectAlert Licence Agreement") dated March 27, 1998, May 1, 1998 and October 23, 2001 between the Corporation and the ColorectAlert Inventor, the Corporation acquired a licence for all diagnostic applications and products which incorporate or make use of this technology as well as the licence for the two existing U.S. patents and one Japanese patent. Pursuant to the terms of the ColorectAlert Licence Agreements, the Corporation is required to make payments upon achieving certain milestones leading up to FDA clearance of this test, and royalty payments based on revenues from sales of this technology. The ColorectAlert Licence Agreements do not provide for a fixed termination date and may only be terminated by the parties in the event of a material breach by the other party.

A second colorectal cancer test, ColoPath, is a patented technology that detects another marker believed to be associated with cancer of the colon or rectum. The technology was developed by Procyon BioPharma Inc. ("Procyon"). The Corporation entered into an agreement with Procyon dated March 19, 2001, as amended, (the "Procyon License Agreement") whereby the Corporation licensed the intellectual property, including patent rights and trademarks of ColoPath and has the right to develop, manufacture, market and distribute the ColoPath technology exclusively on a global basis. Pursuant to the terms of the Procyon License Agreement, all new patents will be owned by the Corporation. Procyon is entitled to payments based on the completion of milestones as well as a royalty payment based on sales of all mucus-based colorectal cancer tests. The Procyon Licence Agreement does not have a fixed termination date.

The Technologies

The ColorectAlert test detects the presence of a specific sugar in the rectal mucus of individuals who may have colorectal cancer or, potentially, precancerous polyps. This sugar is detected by a chemical reaction performed on a specimen placed on a test membrane following routine digital rectal examinations and does not require a blood sample. The same technology is being adapted for the detection of lung cancer and breast cancer, and could potentially be adapted for the detection of additional cancers.

ColoPath is a similar assay to ColorectAlert and is being evaluated in conjunction with the ColorectAlert test.

Development History and Clinical Findings

The Corporation has conducted clinical trials to validate the ColorectAlert Inventor's data that had been collected on a few thousand patients. In accordance with a sponsored research agreement (the "St. Michael's Agreement") dated November 30, 1998, the Corporation completed a prospective clinical trial in December 1999 at St. Michael's Hospital ("St. Michael's"), Wellesley Central Site, Toronto, Ontario, with Dr. N. Marcon as principal investigator. The clinical trial examined ColorectAlert to determine its added benefit, relative to FOBT and CEA, for the early diagnosis of colorectal cancer and precancerous polyps in high-risk patients. A total of 600 patients were tested over a 12-month period. The results of the trial indicated that ColorectAlert was equally sensitive and more specific, on its own, than FOBT testing in these patients. These results were presented at the Digestive Disease Week Meeting held on May 22, 2000 in San Diego, California.

Two clinical trials involving 1,250 patients were completed in 2002 at St. Michael's Hospital, Toronto to evaluate ColoPath and to determine the reproducibility of ColorectAlert as well as to determine the effectiveness of ColorectAlert in an unprepared bowel.

In the first study, 750 patients provided two samples each that were processed in separate labs at different times to demonstrate that ColorectAlert results are reproducible and consistent. All patients also underwent a colonoscopy, allowing for further correlation between ColorectAlert values and colonoscopy results. All of the patients in the study were scheduled for colonoscopy, but for various reasons such as having symptoms or a family history of the disease, or as a result of screening. The second study examined 500 patients scheduled for colonoscopy, and took two samples from each patient. The first sample was taken prior to bowel cleansing and the second was taken after cleansing to determine the effect of cleansing on ColorectAlert results.

The combined results of these studies, which were presented at the American Association for Cancer Research ("AACR") meeting in Washington D.C. in 2003, showed that the ColorectAlert test result was correlated with the presence of colorectal cancer, including Duke's Stage A and B disease.

These results support management's belief that the test undergoing trials could lead to earlier detection of cancer and greater accuracy in diagnosis.

Patents

The Corporation acquired the rights to two U.S. patents and one Japanese patent for ColorectAlert as well as the rights to worldwide granted patents for ColoPath. A patent involving the spectrophotometric measurement of colour-based biochemical and immunological assays has been filed, on a worldwide basis, and is applicable to these technologies.

Competition

CEA

The only FDA-approved tumor marker for colorectal cancer is carcinoembryonic antigen ("CEA") and is marketed by several companies. Its sensitivity is dependent on the stage of disease according to the Duke's Classification Method as follows:

Stage A:	7%
Stage B:	21%
Stage C:	28%
Stage D:	64%

In addition, CEA may have value in prompting second look surgery since rising values may be indicative of recurrence. CEA is also useful in monitoring response to chemotherapy.

To the best of the Corporation's knowledge, there are no other FDA-approved tumor markers for colorectal cancer although several are believed to be in development.

FOBT

FOBT has sensitivity of 50% for cancer (Clinical Database “Should All People Over the Age of 50 have Regular Fecal Occult -Blood Tests?”, April 6, 1998) and a positive predictive value of 2%-17% (“Fecal Occult Blood Testing for Colorectal Cancer, Can We Afford to do This?” Alquist, D.A. Gastroenterol Clin. North. Am., 1997). This predictive value leads to unnecessary cost and patient inconvenience and anxiety due to unnecessary colonoscopies. In addition, compliance with fecal occult blood testing procedures (e.g. dietary restrictions) is estimated to be only 35-50% (Clinical Database, April 16, 1998). The Corporation believes that many physicians are dissatisfied by fecal occult blood testing in general and would prefer to have an improved test.

Sigmoidoscopy examines the lower colon and is expensive (US\$100-US\$200/test), may cause complications (bowel perforations) and is not well accepted by the patient. Sensitivity varies with the type of instrument and the skill of the physician. The best reported values are 40-65%.

Colonoscopy is the most effective test for detecting cancerous and precancerous polyps, as the entire colon can be visualized. However, the use of colonoscopy as a screening technology is extremely limited due to the fact that it is a very invasive and expensive procedure. Although virtual colonoscopy, which is non-invasive, is being used for screening, the technology is still being refined and is relatively high cost.

Management of the Corporation is aware of other diagnostic tests under development that may be useful for the detection of all colorectal pathology and is currently monitoring their progress. Some of the firms involved in the development or marketing of such products include Enterix Inc., EXACT Sciences Corporation and E-Z-EM Inc.

Key Markets

The ColorectAlert test, following the appropriate regulatory clearance, could be used in the laboratory and, potentially, physicians’ offices. Theta estimates that the global market for all cancer detection products, including mammography, was US\$2.0 billion in 1999, growing to US\$2.8 billion in 2005. The U.S. market is estimated to be 36% of the total worldwide market and is expected to grow at 15% until 2005. The Japanese market is second largest at 26% of the global market and is estimated to grow at 18% until 2005 (*Theta Reports, High Growth Diagnostic Markets, Report No 1045, September 2000*).

Lung Cancer Test (LungAlert)

Pathology

Lung cancer is the number one cause of cancer-related death for both men and women in North America. In the majority of cases, lung cancer begins in the lining of the bronchi and slowly moves down to the lungs. Initially the cancer does not cause a solid mass tumor and results in few or no symptoms. More than 85% of lung cancer cases can be directly or partly attributed to smoking (*American Lung Association*).

There are two main types of lung cancer, Small Cell Lung Cancer (“SCLC”) and Non-Small Cell Lung Cancer (“NSCLC”). SCLC can be further subdivided into two stages, limited stage and extensive stage. In limited stage, the tumor is confined to its original area and has not spread to other parts of the body. In extensive stage lung cancer, the tumor has metastasized.

NSCLC is classified under three subgroups and assigned to one of four stages. The subgroups are:

Squamous cell carcinoma:	Always associated with smoking. Usually starts in bronchi.
Adenocarcinoma:	Begins in mucus glands usually near the periphery of the lung.
Large-cell undifferentiated	May appear in any part of the lung. Tends to grow and spread quickly.

Lung cancer stages are:

T1:	Tumor is smaller than 3 cm and has not spread to the main branches of the bronchus.
T2:	Tumor is larger than 3 cm. Cancer has spread to the main bronchus. Cancer partially clogs airway but does not cause pneumonia.
T3:	Tumor has spread to the chest wall and/or the diaphragm. The cancer is within 2 cm of the trachea. One or both lungs collapse.
T4:	Metastatic spread. Two or more tumor modules are present in the same lobe with malignant pleural effusion.

Common symptoms of advancing lung cancer include an excessive cough, worsening breathlessness, weight loss and fatigue.

Lung Cancer Screening

Lung cancer screening is not currently conducted in any country, with the exception of Japan, due to the poor health economic results of previous screening initiatives. The Japanese government covers costs relating to an annual X-ray and sputum cytology for those in the “high risk” category. This group is defined as individuals over the age of 45 and who have been heavy smokers for the past 20 years or longer.

Although a number of tests are available, they cannot be used cost effectively to identify lung cancer in the early stages. Since the determination of stage has important therapeutic and prognostic implications, careful initial diagnostic evaluation defining the location and extent of primary tumor is critical for the appropriate care of the individual. In the absence of an effective treatment for advanced stage disease, management believes that early detection for lung cancer is critical. To be effective, screening must accurately identify early stage disease in asymptomatic individuals. Screening must also be cost effective and socially acceptable to ensure compliance. Management is aware of five diagnostic options available to screen for lung cancer: X-rays, conventional sputum cytology, spiral CT, Positron Emission Tomography and bronchoscopy.

1. An X-ray is a simple and safe procedure that is relatively ineffective. Less than 40% of all lung cancers can be detected by this screening method.
2. Conventional Sputum Cytology has been used for over 50 years; however it is the least sensitive and only able to identify 20% of lung cancer cases.

3. Spiral CT has been hailed as the technology that holds the greatest promise for cost effectively screening for lung cancer. Although it holds the ability to detect approximately 70% of lung cancers, it has a high cost which translates into \$300-\$600 per test.
4. Positron Emission Tomography is the most accurate screening test available at over 90% sensitivity. Since it is extremely expensive at \$2,500 per patient, widespread use would be unfeasible.
5. Bronchoscopy is used as a final diagnostic option prior to surgery. It is highly invasive and results in a 0.2% mortality rate with the majority of patients unable to return to daily routines for several weeks or months.

Market

According to the American Cancer Society, in the U.S. in 2004 there will be an estimated 173,770 new cases of lung cancer and an estimated 160,440 lung cancer deaths, representing 28% of all cancer deaths (*American Cancer Society, Cancer Facts and Figures, 2004*). Lung cancer causes more deaths in both North American men and women than any other cancer. Only 16% of lung cancers are diagnosed at an early, localized stage (*American Cancer Society*). Management believes that this fact alone demonstrates the need for an effective early screening test for lung cancer.

The Opportunity

LungAlert is based on a modified version of the ColorectAlert technology, using a sputum sample instead of a rectal mucus sample. See "Business of the Corporation - Colorectal Cancer Tests - The Opportunity" for licensing and technology information.

Development History and Clinical Findings

The Corporation has developed a prototype of the LungAlert technology suitable for clinical evaluation. The Corporation undertook a pilot study to determine if the ColorectAlert technology could be used as a screening test for lung cancer. Seventy-six patients were tested, consisting of 24 healthy volunteers, 29 individuals with benign lung disease, and 23 individuals with lung cancer. The study showed a sensitivity of 87% and a specificity of 76%. These results were presented at the American Thoracic Society ("ATS") Meeting in May 2001, and were also published in the Journal of Clinical Ligand Assay Society in the spring of 2002.

In accordance with a sponsored research agreement (the "St. Joseph's Agreement") dated January 25, 2002, the Corporation began a prospective clinical trial involving 500 patients at St. Joseph's Hospital ("St. Joseph") and McMaster University, Hamilton, Ontario with Dr. P. Gerard Cox and Dr. John Miller as principal investigators. The clinical trial is designed to determine LungAlert values in individuals with lung cancer, in individuals with benign lung disease, and in healthy smokers. An abstract based on interim data was accepted by the American Association For Cancer Research ("AACR") and published in April 2003 showing that LungAlert detected 57% of early-stage lung cancer and had an overall sensitivity of 65% and specificity of 94%. Further findings from this study will be presented in May 2004 at the American Thoracic Society International Conference, a premier global forum for physicians.

In October 2003, the Corporation announced that LungAlert was included in the National Cancer Institute's International Early Lung Cancer Action Program ("IELCAP"). I-ELCAP is a major

international study on lung cancer screening, taking place at more than 20 sites around the world. LungAlert has been integrated into a sub-study of I-ELCAP at the lead Canadian site at the Princess Margaret Hospital/University Health Network in Toronto, Ontario, led by principal investigator Dr. Heidi Roberts.

As part of the study, 1,000 high-risk patients will undergo low-dose computed tomography (CT scan) twice, once at baseline and once at a one-year follow-up. Patients will also be tested with LungAlert at these times. Data from the study will help determine the ability of LungAlert to detect cancers among a high-risk population, and will also provide data on the relationship between LungAlert values and the stage and location of cancer.

Patents

Patent coverage for LungAlert is the same as patent coverage for ColorectAlert. See “Business of the Corporation - Colorectal Cancer Tests – Patents”.

Competition

To the Corporation’s knowledge, there are no FDA-approved tumor markers for lung cancer, although several are believed to be in development.

Several tests for lung cancer exist but due to their low ability to detect cancer, or their high cost, management believes that they are not suitable for cancer screening.

Management of the Corporation is aware of other diagnostic tests under development that may be useful for the detection of lung cancer and is currently monitoring their progress. Some of the firms involved in the development or marketing of such products are Biomoda Inc. and Xillix Technologies Corp.

Key Markets

The LungAlert test may be suitable for use in both the laboratory and potentially the physician’s office with the appropriate regulatory clearance for each use. The initial target population are smokers and former smokers as smoking causes more than 85% of lung cancer cases (*American Lung Association*).

Prostate Cancer Test

In August 2000, the Corporation licensed the patents for a prostate cancer test from Dr. S. Hakky of Largo, Florida. In 2003, the Corporation discontinued further development of this technology.

Breast Cancer Test

Pathology

Breast cancer is the most common cancer among women, other than skin cancer. It is the second leading cause of cancer death in women, after lung cancer. (*American Cancer Society*)

Breast cancer may be non-invasive or invasive. The most common type of non-invasive breast cancer is ductal carcinoma in situ, which is confined to the lining of the breast ducts. The most common type of invasive breast cancer is infiltrating ductal carcinoma (“IDC”), which starts in a milk passage or duct,

breaks through the wall of the duct, and invades the fatty tissue of the breast. IDC accounts for about 80% of invasive breast cancer (*American Cancer Society*).

Breast cancer is categorized into the following stages:

Stage 0: Non-invasive carcinoma

Stage I: The tumor is no more than about an inch across and cancer cells have not spread beyond the breast.

Stage II:

- Tumor in the breast is less than 1 inch across and the cancer has spread to the lymph nodes under the arm; or
- Tumor is between 1 and 2 inches (with or without spread to the lymph nodes under the arm); or
- Tumor is larger than 2 inches but has not spread to the lymph nodes under the arm.

Stage III:

- Tumor in the breast is large (more than 2 inches across) and the cancer has spread to the underarm lymph nodes; or
- Cancer is extensive in the underarm lymph nodes; or
- Cancer has spread to lymph nodes near the breastbone or to other tissues near the breast.

Stage IV: Metastatic cancer

Common symptoms of breast cancer include a swelling of part of the breast, skin irritation or dimpling, nipple pain or redness, nipple discharge or a lump in the underarm area. However, early stage breast cancer frequently has no symptoms.

Breast Cancer Screening

American Cancer Society guidelines for the early detection of breast cancer recommend an annual mammogram for women age 40 and older and a clinical breast examination (“CBE”) for women in their 20s and 30s every three years and annually for women in their 40s. Breast self-examination may also help to detect changes in the breast.

Market

About 215,990 women in the U.S. are expected to be diagnosed with have invasive breast cancer in 2004, and about 40,110 women will die from the disease (*American Cancer Society, Cancer Facts and Figures, 2004*). There are slightly over 2 million women living in the U.S. who have been treated for breast cancer. Breast cancer is the leading cause of death in women between the ages of 40 and 55 (*U.S. National Breast Cancer Foundation*). When breast cancer is found early, the five-year survival rate is 96%.

The incidence of breast cancer is very low for women in their 20s, gradually increases and plateaus at the age of 45 and increases dramatically after 50. Fifty percent of breast cancer is diagnosed in women over 65, which indicates the ongoing necessity of annual screening.

The Opportunity

The Corporation's breast cancer test is based on a modified version of the ColorectAlert and LungAlert technology but uses a sample of nipple-aspirate fluid, which is derived from the mammary ducts and expressed through the nipple.

Development History and Clinical Findings

The Corporation has developed a prototype of the breast cancer test suitable for clinical evaluation. The Corporation has tested a small number of samples (100) in a pilot study at the University of Texas M.D. Anderson Cancer Center. This study demonstrated the ability of the test to distinguish between cancerous and non-cancerous breast samples. This research was accepted for presentation at the American Association for Cancer Research meeting in 2003 and was published in the *Proceedings of the AACR* in April 2003.

The Corporation is working to expand clinical data through larger studies.

Patents

Patent coverage for the breast cancer test is the same as patent coverage for ColorectAlert and LungAlert. See "Business of the Corporation – Colorectal Cancer Test – Patents".

Key Markets

The breast cancer test, following the appropriate regulatory clearance, could be used in physicians' offices as part of risk assessment for breast cancer.

Other Product Development Programs

To date, the Corporation has identified a number of other technologies, several of which are under evaluation. The Corporation is currently assessing likely proprietary position and market potential for these technologies as well as evaluating the technological and regulatory obstacles that must be overcome with each program.

Patent and Proprietary Protection

The Corporation seeks to acquire processes and/or products or acquire licences for processes and/or products, which have existing proprietary protection. If patents have not yet been issued on a technology, the Corporation will review the patent applications, if any, and examine the patentability of the technology in question. In some cases, the Corporation may actually file patent applications for technologies that it owns or in respect of which it has acquired a licence and then further developed. Such applications may cover composition of matter, the production of active ingredients and their novel applications. The Corporation has acquired, by licence or assignment, rights in patents and applications filed in Canada, the U.S. and internationally.

The Corporation retains independent patent counsel where appropriate. Management of the Corporation believes that the use of outside patent specialists ensures prompt filing of patent applications as well as the ability to access specialists in various areas of patents and patent law to ensure complete patent filing.

Patent positions can be uncertain and involve many complex legal, scientific and factual questions. While the Corporation intends to protect its valuable proprietary information and believes that certain of its information is novel and patentable, there can be no assurance that: (i) any patent application owned by or licensed to the Corporation will be approved in all countries; (ii) proceedings will not be commenced seeking to challenge the Corporation's patent rights or that such challenges will not be successful; (iii) proceedings taken against a third party for infringement of patent rights will be successful; (iv) processes or products of the Corporation will not infringe upon the patents of third parties; or (v) the scope of patents issued to or licensed by the Corporation will successfully prevent third parties from developing similar and competitive products. It is not possible to predict how any litigation may affect the Corporation's efforts to develop, manufacture or market products. The cost of litigation to uphold the validity and prevent infringement of the patents owned by or licensed to the Corporation may be significant.

Issues may arise with respect to claims of others to rights in the patents or patent applications owned by or licensed to the Corporation. As the industry expands, and more patents are issued, the risk increases that the Corporation's processes and products may give rise to claims that they infringe the patents of others. Actions could be brought against the Corporation or its commercial partners claiming damages or an accounting of profits and seeking to enjoin them from clinically testing, manufacturing and marketing the affected product or process. If any such action were successful, in addition to any potential liability for damages, the Corporation or its commercial partners could be required to obtain a licence in order to continue to manufacture or market the affected product or use the affected process. There can be no assurance that the Corporation or its commercial partners could prevail in any such action or that any licence required under any such patent would be made available or, if available, would be available on acceptable terms. If no licence is available, the Corporation's ability to commercialize its products may be negatively affected. There may be significant litigation in the industry regarding patents and other intellectual property rights and such litigation could consume substantial resources. If required, the Corporation may seek to negotiate licences under competitive or blocking patents that it believes are required for it to commercialize its products.

Although the scope of patent protection ultimately afforded by the patents and patent applications owned by or licensed to the Corporation is difficult to quantify, management of the Corporation believes that such patents will afford adequate protection for it to ensure exclusivity in the conduct of its business operations as described herein. The Corporation also intends to rely upon trade secrets, unpatented proprietary know-how and continuing technological innovation to develop and maintain its competitive position. To protect these rights, the Corporation requires all employees and consultants to enter into confidentiality agreements with the Corporation. There can be no assurance, however, that these agreements will provide meaningful protection for the Corporation's trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, in the absence of patent protection, the Corporation's business may be adversely affected by competitors who independently develop substantially equivalent technology.

The Corporation's success depends, in part, on its ability to obtain patents, maintain its trade secrets and operate without infringing the proprietary rights of third parties. See "Risk Factors - Patents and Proprietary Technology".

Competition

The medical device industry is dominated by a few major companies which are involved in the research, development, manufacture and marketing of products. Beyond these major players, a number of relatively new firms have been established, with a focus on developing improved products. The industry is characterized by extensive research efforts, technological change and intense competition. Competition can be expected to increase as technological advances are made and new diagnostic tools are developed. Competition in the industry is primarily based on: (i) product performance, including efficacy and safety; (ii) price; (iii) acceptance by physicians and various payers such as governments and HMOs; (iv) marketing; and (v) distribution. The availability of patent protection in the U.S. and elsewhere, and the ability to obtain governmental approval for testing, manufacturing and marketing, are also important factors.

Other groups active in this industry include educational institutions and public and private research institutions. These institutions are becoming more active in seeking patent protection and licensing arrangements to collect royalties for use of technology that they have developed. They are also becoming increasingly competitive in recruiting personnel from the limited supply of highly qualified clinical physicians, academic scientists and other professionals.

Competitors of the Corporation may: (i) use different technologies or approaches to develop products similar to products which the Corporation is seeking to develop; (ii) develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any developed by the Corporation; and (iii) succeed in obtaining regulatory approval of such products before the Corporation obtains approval of its products. There can be no assurance that the Corporation's products will compete successfully or that research and development will not render the Corporation's products obsolete or uneconomical. See "Risk Factors - Competition".

In the long term, the Corporation believes that its ability to compete effectively will be based on its ability to create and maintain scientifically advanced technology, develop superior products, attract and retain scientific personnel with a broad range of technical expertise and capability, obtain proprietary protection for its products and processes, secure the required government approvals on a timely basis, identify and successfully pursue research and development projects for which significant market opportunities exist or are likely to develop, and manufacture and successfully market its products. The competition for personnel is intense and the Corporation cannot guarantee that personnel who are currently working on behalf of the Corporation will remain or that sufficiently qualified employees can be found to replace them. The loss of key employees and/or key contractors may affect the speed and success of product development. See "Risk Factors - Dependence on Key Employees".

Once the products for which the Corporation has received patents are on the market, those products will compete directly with other products that have been developed for the same predictive testing purpose or therapeutic indication. When the patents covering these products expire, the products previously covered by the patents could face competition from generic products, which are usually priced much lower than the original products.

Raw Materials

Although the Corporation manufactures a few components in its own laboratory, most of the raw materials used in the production of the Corporation's products are generic laboratory materials that are readily available to the Corporation from commercial sources. The prices of these various materials have

remained stable over the past five years. Any volatility in the prices of these raw materials would not have a material impact on world markets or on the Corporation due to the widely available nature of these raw materials and the relatively small quantities that are used by the Corporation at any one time.

Regulatory Requirements

The Corporation is in the process of developing novel diagnostic devices. These devices are regulated differently in each country in which the Corporation wishes to have its products sold. The regulations governing the sale and distribution of devices and the time taken for this approval process can vary more widely than for the approval of pharmaceuticals. However, it is generally recognized that the requirements for diagnostic products such as those that the Corporation is in the process of developing are less arduous than those for pharmaceuticals.

Canada

The Canadian health care industry is regulated by the HPB. This federal agency has a role similar to that of the FDA and has responsibility for regulating drugs for both human and animal use, cosmetics, medical devices, radiation emitting devices, foods and food additives, chemicals and other products affecting human health. A manufacturer is required to follow specific regulations referred to as current Good Manufacturing Practice ("GMP") regulations in the manufacture of such products. Regulations imposed by federal, provincial, state and local authorities in Canada and the U.S. as well as their counterparts in other countries, are a significant factor in the conduct of the development, manufacturing and eventual marketing activities for the proposed products.

U.S.

As the most significant market for the Corporation's products is in the U.S., and it is generally accepted that the FDA has the most stringent device approval requirements, a general review of the FDA regulations follows.

If a device is considered to be substantially equivalent to existing devices already marketed, it may receive a 510(k) clearance. Under this clearance, the FDA will send the manufacturer a market clearance letter called a substantially-equivalent letter. Although this process can be as short as 60 days, it is typical for a 510(k) approval to take 90 to 120 days. If a device does not qualify for a 510(k), a pre-market approval ("PMA") process may be required. The length of the PMA process depends largely on the nature of the device and the diagnosis undertaken through the use of the device and the resulting impact on clinical trial endpoints and design. Increasingly, the FDA is creating a more user-friendly regulatory environment, and, as a result, even the PMA process can proceed expeditiously.

Many medical devices sold in the U.S. today have been cleared for commercial distribution and marketing by PMA. A PMA must be submitted to the FDA if a company wants to introduce a device with a new intended use into commercial distribution. Under a PMA, the FDA is notified as to a company's intent to market a device. If the application is accepted, this signifies only acceptance of the application and not a clearance to sell the device. Under the PMA guidelines, the FDA requires the submission and review of valid scientific evidence to determine whether a reasonable assurance exists that the device is safe, effective and has clinical utility. The collection and evaluation of clinical data to demonstrate the safety and efficacy of a medical device are essential for the ultimate approval of that device. Valid scientific evidence as currently defined by the FDA is limited to well-controlled investigations, including (where applicable) blinding and randomization of clinical trials.

The products that the Corporation is currently developing may ultimately be subject to the demanding and time-consuming PMA approval procedure. The regulations defined by these procedures cover not only the form and content of the development of safety and efficacy data regarding the proposed product, but also impose specific requirements regarding manufacture of the product, quality assurance, packaging, storage, documentation and record keeping, labelling, advertising and marketing procedures. The process of conducting the clinical trials and gathering, compiling and submitting the data required to support a PMA or facility approval is expensive and time-consuming, and there can be no assurance that the FDA will approve a PMA or a manufacturing facility submitted to it in a timely manner, or at all. See “Risk Factors - Government Regulation”.

In order to obtain approval, an applicant must submit, as relevant for the particular product, proof of safety, purity, potency and efficacy. In most cases, such proof entails extensive pre-clinical, clinical and laboratory tests. The testing, preparation of necessary applications and processing of those applications is expensive and time-consuming and may take several years to complete. There is no assurance that the regulator will act favourably or quickly in making such reviews and approving products for sale. The Corporation may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approval or licences, which could delay or preclude the Corporation from marketing its products. Conditions could also be placed on any such approvals that could restrict the commercial applications of such products. With respect to patented products or technologies, delays imposed by the government approval process materially reduce the period during which the Corporation will have the exclusive right to exploit them. This occurs because patent protection lasts only for a limited time, beginning on the date the patent is first granted (in the case of U.S. patent applications) or when the patent is first filed (in the case of patent applications filed in the European Community and Canada).

Among the requirements for product approval is the requirement that prospective manufacturers conform to the FDA’s and HPB’s current GMP standards, which thereafter must be followed at all times. In complying with GMP standards, manufacturers must continue to expend time, money and effort in production, record keeping and quality control to ensure technical compliance. Continued compliance is necessary for all products with all requirements of the applicable legislation and the conditions laid out in an approved application, including, but not limited to, product specification, manufacturing process, labelling, promotional material, record keeping and reporting requirements. Failure to comply, or the occurrence of unanticipated adverse effects during commercial marketing, could lead to the need for product recall, or regulator-initiated action such as the suspension of manufacturing or seizure of the product, which could delay further marketing until the products are brought into compliance. The regulator may also request a voluntary recall of a product. The regulator may also require post-marketing testing and surveillance to monitor the record of the product and continued compliance with regulatory requirements.

Europe

The CE (Conformité Européene) mark is a mandatory European mark for medical devices and in vitro diagnostic devices (IVD) that indicates conformity of the product with the essential health and safety requirements of the applicable European directive(s).

Before placing a medical device or IVD on the European Union (E.U.) market, the manufacturer must subject the product to the conformity assessment procedure that is provided in the applicable Directive, with the intention of affixing a CE-mark to the product. Certain products, such as the Corporation’s consumer version of the skin cholesterol test, currently in development, will require a third-party conformity assessment to be carried out by a Notified Body, which is a public or private company

designated by Member States of the European Union to assess a product's conformity with the essential requirements of the medical device and IVD directives. Other products, such as Cholesterol 1,2,3, fall under the "Other" Category of IVDs. Products in this category can be self-CE-marked by the manufacturer without the involvement of a Notified body. As well, all manufacturers outside of the E.U. are required to designate an Authorized Representative in the E.U. who can respond to queries from Member States and customers with regard to a CE-marked product on behalf of the manufacturer.

Once a product is CE-marked, it may be placed on the E.U. market and freely circulated throughout Member States.

The Corporation received HPB clearance for Cholesterol 1,2,3 in 2001, 510(K) clearance from the FDA for Cholesterol 1,2,3 in June 2002 and was CE-marked on September 5, 2002 for European marketing of Cholesterol 1,2,3. The Corporation's marketing partner for Canada and select U.S. markets, McNeil Consumer Healthcare, commenced an education and awareness program in the fall of 2003 and expects to make the skin cholesterol technology available in 2004. The other technologies of the Corporation are in various stages of clinical trials in the U.S. and Canada, and thus the timing for receipt of HPB and FDA clearance is uncertain. Generally, research and clinical data used to receive regulatory approval in one jurisdiction may be used for regulatory submissions in other jurisdictions.

While the Corporation has had success in receiving HPB and FDA clearance for Cholesterol 1,2,3, the product testing and approval/clearance process for the Corporation's other technologies could take a number of years and involve the expenditure of significant resources. There can be no assurance that clearance will be granted on a timely basis, or at all.

Employees

The Corporation currently employs 17 full-time people, nine of whom are located at its head office in Toronto, Ontario and eight at its research laboratory in Hamilton, Ontario. In addition, the Corporation has contractual arrangements with a number of research scientists and organizations that provide staff and related services. These contracts provide flexible and directed research staff to the Corporation on an as-needed basis.

RISK FACTORS

No Assurance of Successful Development

Prospects for emerging companies in the human diagnostics industry generally may be regarded as uncertain given the inherent nature of the industry and, accordingly, investments in such companies should be regarded as speculative. There can be no assurance that the research and development organized or conducted by the Corporation will result in commercially viable products. To achieve profitable operations, the Corporation, alone or with others, must successfully develop, introduce and market its products. As at the date hereof, the Corporation has not introduced any product, diagnostic or otherwise, into the market. In order to obtain regulatory approvals for the products being developed and to achieve commercial success, human clinical trials must demonstrate that the products are safe for human use and that they show efficacy. Unsatisfactory results obtained from a particular study relating to a program may cause the Corporation to abandon its commitment to that program. No assurances can be provided that any future human tests, if undertaken, will yield favourable results.

No Assurance of Successful Marketing

The Corporation has no experience in marketing its products and intends to seek one or more partners, such as major diagnostic or pharmaceutical companies, to undertake marketing on its behalf. There can however be no assurance that such efforts will be successful. If the Corporation relies on third parties to market its products, the commercial success of such products may be outside of its control. Moreover, there can be no assurance that providers, payers or patients will accept the Corporation's products, even if the Corporation's products prove to be safe and effective and are allowed for marketing by the HPB and other regulatory authorities. Market penetration shortfalls could arise due to reimbursement difficulties with government agencies and third-party insurers, which could hamper the speed with which the products are adopted by the medical community and by the public. Market penetration of the Corporation's products will be influenced by factors including the cost-effectiveness and the overall economic benefits that they offer.

Manufacturing

The Corporation relies on third parties to manufacture and formulate its products for clinical trials and for eventual commercial sale. The ability to ensure a continued supply of products on a timely basis is not entirely within the control of the Corporation. If the Corporation cannot obtain materials in a timely fashion, the progress of the Corporation's clinical trials and product sales will be negatively impacted.

Lack of Operating Profits

To date, the Corporation has not generated revenues to offset its research and development costs and operating costs and accordingly has not made an operating profit. See "Selected Financial Information", and "Management's Discussion and Analysis of Financial Condition and Results of Operations". While the Corporation has historically benefited from the inclusion of government grants and federal and provincial refundable scientific investment tax credits ("ITCs") in its annual revenue, there can be no assurance that grants and ITCs will continue to be available to the Corporation or, if so, at what levels. There can be no assurance that the Corporation will ever achieve significant revenues or profitable operations.

Liquidity and Capital Resources

Management believes that, based upon historic cash expenditures and the current the expectation that revenues from strategic alliances and product sales will begin in 2004, its current cash resources will be sufficient to meet its planned operating and capital requirements through fiscal 2005. However, the Corporation's future capital requirements will depend on many factors, including continued progress in diagnostic development programs, pre-clinical and clinical evaluation, time and expense associated with regulatory filings, prosecuting and enforcing its patent claims, and costs associated with obtaining regulatory approvals. In order to meet such capital requirements, the Corporation will consider out-licensing its products under collaborative research and development arrangements, and additional public or private financing (including the issuance of additional equity securities) to fund all or a part of particular programs. There can be no assurance that additional funding will be available or, if available, that it will be available on acceptable terms. If such funding is not available, the Corporation may be forced to reduce or eliminate expenditures relating to specific programs relating to the development, testing, production or marketing of its proposed products, or may have to obtain funds through arrangements with corporate partners that require the Corporation to relinquish rights to certain of its technologies or products. There can be no assurance that the Corporation will be able to raise additional

capital if its capital resources are exhausted. See “Management’s Discussion and Analysis of Financial Condition and Operating Results”.

Competition

Technological competition in the diagnostic industry is intense. The Corporation competes with other companies to license and develop products aimed at diagnosing similar conditions. Many of these companies have substantially greater resources than the Corporation. There can be no assurance that the Corporation will continue to be able to license technology or that developments by others will not render the Corporation’s products or technologies non-competitive. See “Business of the Corporation – Coronary Artery Disease Risk Assessment Technology”, “Business of the Corporation - Colorectal Cancer Tests (ColorectAlert and ColoPath)”, “Business of the Corporation – Lung Cancer Test (LungAlert)”, “Business of the Corporation – Breast Cancer Test”, “Business of the Corporation – Prostate Cancer Test”, “Business of the Corporation - Competition” and “Business of the Corporation - Patent and Proprietary Protection”.

Patents and Proprietary Technology

The Corporation’s success will depend, in part, on its ability to acquire patents or licences, maintain trade secret protection and operate without infringing the proprietary rights of third parties. The Corporation has filed patent applications in the U.S. and other jurisdictions. There can be no assurance that the Corporation’s outstanding patent applications will be allowed, that the Corporation will gain access to additional proprietary products that are patentable, that issued patents will provide the Corporation with any competitive advantages or will not be challenged by any third parties, or that the patents of others will not have an adverse effect on the ability of the Corporation to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the Corporation’s products or design around the patented products developed by the Corporation.

The Corporation may be required to obtain licences under patents or other proprietary rights of third parties. No assurance can be given that any licences required under any such patents or proprietary rights will be available on terms acceptable to the Corporation or that such licences will be available at all. If the Corporation does not obtain such licences, it could encounter delays in introducing one or more of its products to the market while it attempts to design around such patents, or could find that the development, manufacture or sale of products requiring such licences could be foreclosed. In addition, the Corporation could incur substantial costs in defending itself in suits brought against it on such patents or in suits in which the Corporation attempts to enforce its own patents against other parties. Also, the Corporation could be liable for damages or an accounting of profits if it were unsuccessful in defending itself in a suit for infringement of a patent. See “Business of the Corporation - Patent and Proprietary Protection”.

Government Regulation

Securing regulatory acceptance for the marketing of diagnostics products from the HPB in Canada and the FDA in the United States can be a long and expensive process, which can delay product development. Acceptance to market products may be for limited applications or may not be received at all. Such events would have a material adverse effect on the sales and profitability of the Corporation. In addition, the time required to obtain HPB or FDA approval can be extensive. See “Business of the Corporation - Regulatory Requirements”.

Product Liability and Insurance

The sale and use of products under development by the Corporation entails risk of product liability. The Corporation has also agreed to indemnify each of The Cleveland Clinic Foundation, St. Michael's Hospital, St. Paul's Hospital, St. Joseph's Hospital, The Hamilton General Hospital, University of California, University Health Network (Princess Margaret Hospital), Hamilton Health Sciences Corporation, University of Wisconsin Medical School, Johns Hopkins University Medical Center and AtheroGenics, Inc. under their respective clinical trial agreements for such liability.

As the Corporation expands, there can be no assurance that it will be able to obtain appropriate levels of product liability insurance prior to any use of its products in clinical trials or for commercial sale. An inability to maintain insurance on economically feasible terms or to otherwise protect against potential product liability claims could inhibit or prevent the commercialization of products developed by the Corporation. The obligation to pay any product liability claim, or finance the costs of a recall of a product, could have a material adverse effect on the business, financial condition and future prospects of the Corporation.

Dependence on Contract Research Firms

The Corporation's ability to develop products will depend partly on its continuing relationships with contract research firms. The Corporation is dependent on these firms to conduct certain research and development efforts and to access certain equipment and facilities. The loss of such services and access to certain equipment and facilities might impede the achievement of the development objectives. See "Business of the Corporation - Competition".

Future Technology Acquisition Efforts

There are no assurances that the Corporation can successfully identify or negotiate the acquisition of or licences for future technologies.

Dependence on Key Employees

The Corporation's ability to develop products will depend, to a great extent, on its ability to attract and retain highly qualified personnel. Competition for such personnel is intense. The Corporation is highly dependent on the principal members of its management and scientific staff and the loss of their services might impede the development objectives. The persons working with the Corporation are affected by a number of influences outside of the control of the Corporation. The loss of key employees may affect the speed and success of product development.

Market Risk

The common shares the Corporation are speculative securities. There can be no assurance that an active trading market for the common shares will be sustained or that the market price of the common shares will not decline. The trading price of the common shares could also be subject to significant fluctuations. Accordingly, this investment should be considered only by those investors who are able to make a long term investment and can afford to suffer a total loss of their investment in the common shares. An investor should consider the merits of an investment in these securities and should consult professional advisers to assess income tax, legal and other aspects of such an investment.

Economic Environment

Reimbursement for new products has come under scrutiny in an effort to control rising health care costs. In addition to research into a product's safety and efficacy, research must also be carried out to demonstrate cost-effectiveness for reimbursement purposes. This information is required for either government (Canada or E.U.) or third-party insurer purposes (U.S.). Failure to achieve enlistment in reimbursement schedules can have a dramatic impact on a product's market penetration.

Dividends

The Corporation does not anticipate paying dividends in the foreseeable future. See "Selected Financial Information - Dividend Record and Policy".

SELECTED FINANCIAL INFORMATION

Annual Financial Information

The following selected financial information has been derived from the audited consolidated financial statements of the Corporation for the fiscal years ended December 31, 2003 and 2002 and the 11-month period ended December 31, 2001. The information should be read in conjunction with the MD&A and the Annual Report.

	Fiscal Year ended December 31, 2003	Fiscal Year ended December 31, 2002	11 month period ended December 31, 2001⁽¹⁾
Operating Results			
Net sales	Nil	nil	nil
Investment tax credits	\$223,146	\$189,908	\$131,000
Interest income	\$275,322	\$257,407	\$386,580
Net loss	\$4,062,711	\$4,018,262	\$3,245,206
Net loss per share:			
- basic and diluted	\$0.19	\$0.20	\$0.17
Financial Position	December 31, 2003	December 31, 2002	December 31, 2001
Total assets	\$8,074,027	\$11,379,383	\$9,343,958
Long term debt	nil	nil	nil
Shareholders' Equity			
Total shareholders' equity	\$7,438,279	\$10,689,828	\$8,948,696
Cash dividends declared per share	nil	nil	nil

Note:

- (1) In 2001, the Corporation changed its financial year end from January 31 to December 31.

Quarterly Financial Information

The following table is a summary of selected unaudited consolidated financial information of the Corporation for each of the eight quarters ended December 31, 2003:

	First Quarter ending March 31, 2003	Second Quarter ending June 30, 2003	Third Quarter ending September, 30, 2003	Fourth Quarter ending December 31, 2003	Fiscal year ended December 31, 2003
2003					
Net sales	nil	nil	nil	nil	nil
Investment tax credits	\$38,000	\$77,583	\$56,634	\$50,929	\$223,146
Interest income	\$67,207	\$71,202	\$50,108	\$86,805	\$275,322
Net loss	\$811,162	\$832,574	\$992,174	\$1,426,801	\$4,062,711
Net loss per share ⁽¹⁾ :					
- basic and diluted	\$0.04	\$0.04	\$0.05	\$0.06	\$0.19
	First Quarter ending March 31, 2002	Second Quarter ending June 30, 2002	Third Quarter ending September, 30, 2002	Fourth Quarter ending December 31, 2002	Fiscal year ended December 31, 2002
2002					
Net sales	nil	nil	nil	nil	Nil
Investment tax credits	\$20,000	\$79,908	\$45,000	\$45,000	\$189,908
Interest income	\$47,122	\$54,743	\$84,753	\$70,789	\$257,407
Net loss	\$799,121	\$1,192,876	\$1,089,167	\$937,098	\$4,018,262
Net loss per share ⁽¹⁾ :					
- basic and diluted	\$0.04	\$0.06	\$0.05	\$0.05	\$0.20

Note:

- (1) Net loss per share has been calculated on the basis of net loss for the period divided by the weighted average number of common shares outstanding during the period.

Dividend Record and Policy

The Corporation has not declared any dividends on its shares. The board of directors of the Corporation does not currently anticipate paying any dividends on its common shares in the foreseeable future but

intends to retain earnings to finance the growth and development of the business of the Corporation. Any future determination to pay dividends will be at the discretion of the board of directors of the Corporation and will depend upon the Corporation's financial condition, results of operations, capital requirements and such other factors as the board of directors of the Corporation deems relevant.

**MANAGEMENT'S DISCUSSION AND ANALYSIS
OF FINANCIAL CONDITION AND OPERATING RESULTS**

Reference is made to the section entitled "Management's Discussion and Analysis" on pages 8 through 16 of the Annual Report, which section is incorporated herein by reference.

MARKET FOR SECURITIES

The common shares of the Corporation are listed and posted for trading on the Toronto Stock Exchange, where they trade under the stock symbol "IMI", and on the American Stock Exchange, where they trade under the stock symbol "IME".

MANAGEMENT AND ADVISORS OF THE CORPORATION

Directors, Executive Officers and Management of the Corporation

The names, municipality of residence, positions held with the Corporation and principal occupations within the previous five years of the current directors and executive officers of the Corporation are as follows:

Name and Municipality of Residence	Position(s) held with the Corporation	Director Since	Principal Occupation during past five years
John C. Carroll ⁽¹⁾⁽²⁾ Toronto, Ontario	Director	June 6, 1994	Director of various public companies
Dr. Michael Evelegh Dundas, Ontario	Executive Vice President, Clinical and Regulatory Affairs	n/a	1996 - present: Executive Vice President, Clinical and Regulatory Affairs of the Corporation
Anthony F. Griffiths ⁽¹⁾⁽²⁾ Toronto, Ontario	Director	July 13, 1995	Director of various public companies
Ronald Hosking Toronto, Ontario	Vice President, Finance and Chief Financial Officer	n/a	1997 - present: Vice President, Finance and Chief Financial Officer of the Corporation
Dr. Brent Norton North York, Ontario	President, Chief Executive Officer and Director	March 17, 1993	1992 - present: President and Chief Executive Officer of the Corporation

Name and Municipality of Residence	Position(s) held with the Corporation	Director Since	Principal Occupation during past five years
David A. Rosenkrantz ⁽¹⁾⁽²⁾ Toronto, Ontario	Director	June 11, 1998	1997 - present: President and Director of Patca Securities Limited; director of various public companies
Stephen A. Wilgar ⁽¹⁾⁽²⁾ Toronto, Ontario	Chairman of the Board and Director	March 17, 1993	1999 - present: retired 1996-1999: President of The Sunblush Technologies Corporation; director of various public companies

Notes:

- (1) Member of the Audit Committee.
- (2) Member of the Compensation Committee.

Each director of the Corporation will hold office until the close of next annual meeting of shareholders of the Corporation or until such director's successor is duly elected or appointed.

Scientific Advisory Board

The Corporation has a Scientific Advisory Board (the "SAB"), the role of which is to provide guidance for new research directions as well as advice on product development plans. The SAB also assists in identifying and defining attractive market niches and in providing industry -related information. The SAB is used on an ad hoc basis. Members of the SAB are not compensated as such although each member is eligible to receive options to purchase common shares of the Corporation pursuant to the Corporation's stock option plan. The members of the SAB are as follow:

Name	Principal Occupation and Background
Dr. John Bienenstock, FRCP, FRCPC, FRSC	Professor, Departments of Medicine and Pathology, Faculty of Health Sciences, McMaster University, Hamilton, Ontario
Dr. Herbert A. Fritsche, Jr., Ph.D.	Professor, Biochemist and Chief of Clinical Chemistry, Department of Pathology and Laboratory Medicine, University of Texas M.D. Anderson Cancer Center, Houston, Texas
Dr. Norman Marcon, MD, FRCP	Chief, Division of Gastroenterology of St. Michael's Hospital, Toronto, Ontario
Dr. Dennis L. Sprecher, MD	Director, Dyslipidemia Discovery Medicine, GlaxoSmithKline, Pennsylvania

Shareholdings

As at the date of this Annual Information Form, the directors and executive officers of the Corporation as a group, owned, directly or indirectly, or exercised control or direction over, 4,695,990 common shares of the Corporation, representing approximately 22% of the issued and outstanding common shares.

Corporate Cease Trade Orders or Bankruptcies

Mr. Anthony Griffiths, a director of the Corporation, was a director of Confederation Life Insurance Company from February 1975 to August 1994. In August 1994, the Ontario Insurance Regulators deemed that it was becoming insolvent and put the company into liquidation.

Mr. Griffiths is a director of Brazilian Resources Inc. On June 10, 2001, the Ontario Securities Commission issued a temporary cease trade order against such company as a result of a failure to file financial statements in a timely manner. The order was rescinded on July 30, 2001.

Mr. Griffiths was a director of Consumers Packaging Inc. ("Consumers") until April 29, 2002. Since May 2001, Consumers had been operating under the protection of the *Companies Creditors' Arrangement Act* with KPMG Inc. acting as monitor. During such period, various Canadian securities commissions issued cease trade orders as a result of failure to file financial statements. Further, during such period, virtually all of Consumers' Canadian and overseas assets were sold and the claims of its secured creditors settled. Each of Consumers' directors resigned on April 29, 2002. On April 30, 2002, Consumers filed an assignment in bankruptcy.

Mr. Griffiths is a director of Slater Steel Inc. which is, as of the date of this Annual Information Form, operating under the protection of the *Companies Creditors' Arrangement Act*.

Mr. David Rosenkrantz, a director of the Corporation, was a director of Northern Mountain Helicopter Group Inc. ("Northern") from 1996 until August 23, 2000. On August 24, 2000, Northern received an order granting protection from its creditors under the *Companies Creditors' Arrangement Act* with the support of its major creditors.

ADDITIONAL INFORMATION

The Corporation will provide to any person, upon request to the Secretary of the Corporation:

- (a) when the securities of the Corporation are in the course of a distribution pursuant to a short form prospectus or a preliminary short form prospectus which has been filed in respect of a distribution of its securities;
 - (i) one copy of this Annual Information Form, together with one copy of any document, or the pertinent pages of any document, incorporated by reference in this Annual Information Form;
 - (ii) one copy of the comparative financial statements of the Corporation for its most recently completed financial year together with the accompanying report of the auditor and one copy of any interim financial statements of the Corporation subsequent to the financial statements for its most recently completed financial year;
 - (iii) one copy of the information circular of the Corporation in respect of its most recent annual meeting of shareholders that involved the election of directors or one copy of any annual filing prepared in lieu of that information circular, as appropriate; and

- (iv) one copy of any other documents that are incorporated by reference into the preliminary short form prospectus or the short form prospectus and are not required to be provided under (i) to (iii) above; or
- (b) at any other time, one copy of any other documents referred to in (a)(i), (ii) and (iii) above, provided that the Corporation may require the payment of a reasonable charge if the request is made by a person who is not a security holder of the Corporation.

Additional information, including directors' and officers' remuneration and indebtedness, principal holders of the Corporation's securities, options to purchase securities and interests of insiders in material transactions, where applicable, is contained in the Corporation's information circular for its most recent annual meeting of shareholders that involved the election of directors. Additional financial information is provided in the Annual Report. A copy of such documents may be obtained upon request from the Secretary of the Corporation.