

IMI INTERNATIONAL MEDICAL INNOVATIONS INC.

ANNUAL INFORMATION FORM

In respect of the year ended

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International
Medical
Innovations Inc.

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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, a reference to “IMI” or “its” and similar words refers to IMI International Medical Innovations Inc., together with its subsidiaries, as the context requires.

Trademarks

Cholesterol 1,2,3™, ColorectAlert™, LungAlert™, ColoPath™ and PREVU (in Canada) are registered trademarks of IMI. All other trademarks or service marks appearing in this Annual Information Form are the trademarks or service marks of the companies that own them.

Forward-Looking Statements

This Annual Information Form contains forward-looking statements. These statements involve known and unknown risks and uncertainties, which could cause IMI’s actual results to differ materially from those in the forward-looking statements. Such risks and uncertainties include, among others, the lack of operating profit and availability of funds and resources to pursue R&D projects, the successful and timely completion of clinical studies, the successful development or marketing of IMI’s products, reliance on third-party manufacturers, the competitiveness of IMI’s products if successfully commercialized, the ability of IMI to take advantage of business opportunities, uncertainties related to the regulatory process, and general changes in economic conditions. In addition, while IMI routinely obtains patents for its products and technology, the protection offered by IMI’s patents and patent applications may be challenged, invalidated or circumvented by IMI’s competitors and there can be no guarantee of its ability to obtain or maintain patent protection for its products or product candidates.

Readers of this Annual Information Form are cautioned not to rely on these forward-looking statements. IMI is providing this information as of the date of this Annual Information Form and does not undertake any obligation to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

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
Adenocarcinoma	A cancer that develops in the lining or inner surface of an organ
Adenoma	A benign tumor that arises in or resembles glandular tissue
Affino-enzymatic	A compound for the visual detection of cholesterol on the surface of the skin
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
Bronchoscopy	A procedure that permits the doctor to see the breathing passages through a lighted tube
CAD	Coronary artery disease, which is a narrowing of the small blood vessels that supply blood and oxygen to the heart
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
CHD	Coronary heart disease, another term for CAD
Chylomicron	A small fat globule composed of protein and lipid (fat) that is found in the blood and lymphatic fluid
CIMT	Carotid intima-media thickness, which is measured by B-mode ultrasound, measures the thickness of the first two inner layers of the carotid artery wall. CIMT is an independent predictor of myocardial infarction (heart attack) and stroke
Colonoscopy	A procedure in which a long flexible viewing tube (a colonoscope) is threaded up through the rectum for the purpose of inspecting the entire colon and rectum and, if there is an abnormality, taking a biopsy of it or removing it
CRP	C-reactive protein is a plasma protein that rises in the blood with the inflammation from certain conditions
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
Duke's Classification Method	A standard classification method for colon and rectal cancer
Extracolonic tissue	Outside the colon
Extrarectal tissue	Outside the rectum

Term	Meaning
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
Framingham Global Risk	Framingham is a landmark study begun in 1948 in which some 12,000 residents of the town of Framingham, MA were enrolled in a study designed to gather medical data. Through this study, major risk factors for heart disease were identified
GMP	Good manufacturing practice
HDL	High-density lipoprotein
HMO	Health maintenance organization
Homocysteine	An amino acid produced by the body. Elevated levels of homocysteine in the blood appear to have a link to elevated risk of cardiovascular disease
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
Hypercholesterolemia	High blood cholesterol
Hyperlipoproteinemia	An excess of lipoproteins in the blood
IDC	Infiltrating ductal carcinoma
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
ISO	International Organization for Standardization
IVD	In vitro diagnostic products are those reagents, instruments and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat or prevent disease
LDL	Low-density lipoprotein
Lipids	A group of organic substances, including fatty acids, which are insoluble in water
Lymphatic	A vessel that conveys lymph fluid through the lymphatic system. Lymph fluid carries cells that help fight infection and disease
Mammography	An X-ray of the breast with the breast in a device that compresses and flattens it
Metastasis	The process by which cancer spreads from the place at which it first arose as a primary tumor to distant locations in the body
Neoplasia	The process of abnormal and uncontrolled growth of cells
NIH	United States Department of Health and Human Services - National Institutes of Health
NSCLC	Non-small cell lung carcinoma
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

Term	Meaning
Polyp	A mass of tissue that develops on the inside wall of a hollow organ, as within the colon or rectum. Polyps may be benign, premalignant, or malignant
PVD	Peripheral vascular disease is a disease of blood vessels outside the heart affecting peripheral circulation as opposed to the cardiac circulation
SCLC	Small cell lung carcinoma
Sigmoidoscopy	Inspection of the rectum and lower colon using a thin lighted tube called a sigmoidoscope
Sonography	A diagnostic medical procedure that uses high frequency sound waves (ultrasound) to produce dynamic visual images of organs, tissues or blood flow inside the body
Spectrophotometer	An instrument for measuring the relative intensities of light in different parts of a spectrum
Squamous cell carcinoma	Cancer that begins in squamous cells --- thin, flat cells that are found in the tissue that forms the surface of the skin, the lining of hollow organs of the body and the passages of the respiratory and digestive tracts
Statins	A class of drug that lowers blood cholesterol
Stenosis	A narrowing
Sterol	A family of fat-like compounds that include cholesterol
TC	Total cholesterol
TEE	Transesophageal echocardiography is a non-invasive diagnostic test (ultrasound). In TEE a small probe is swallowed and echo pictures of the heart are obtained from the esophagus
Vasoactivity	Affecting blood vessels especially in respect to the degree of their relaxation or contraction
VLDL	Very low-density lipoprotein

CORPORATE STRUCTURE

IMI International Medical Innovations Inc. (the “Corporation”) was originally incorporated under the *Canada Business Corporations Act* (“CBCA”) on November 9, 1992. IMI 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 IMI is its wholly-owned subsidiary, IMI International Medical Innovations Inc. (Switzerland), a corporation incorporated under the laws of Switzerland. IMI’s head office and principal place of business is located at 4211 Yonge Street, Suite 615, Toronto, Ontario, M2P 2A9. IMI 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 IMI

Overview

IMI 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. IMI 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 IMI 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.

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

After identifying and evaluating an appropriate technology, IMI purchases or in-licenses the related patents and know-how, completes the development of prototypes and defines the manufacturing protocols. Where appropriate, IMI conducts clinical trials to obtain regulatory approval and register the product for sale. At a point in the development cycle for the technology, IMI 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 processes. Such out-licenses could include research and development support, upfront and milestone payments and an ongoing royalty interest on the sales of these products.

IMI currently owns patents for coronary artery disease (“CAD”) risk assessment technology, which is used to measure skin tissue 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, IMI 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. IMI 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. IMI 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, IMI has negotiated agreements with the inventors of the technologies with the objective of building long-term relationships and mutual cooperation. To date, IMI 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 IMI.

Key Strategic Relationships

On May 10, 2002, IMI entered into an agreement with McNeil Consumer Healthcare ("McNeil"), a Johnson & Johnson company, for the marketing and distribution of IMI'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.

The amended agreement provides McNeil with exclusive rights, in these fields and in this territory, to the present and future versions of IMI's skin cholesterol tests, which are being jointly developed by McNeil and IMI. The agreement has a 15-year term and requires McNeil to purchase IMI's skin cholesterol-based tests and pay ongoing royalties to IMI on sales, in addition to a series of milestone payments, totaling \$3.3 million, which will be based on the licensed products. IMI may terminate this agreement if certain minimum levels of sales of the skin cholesterol test are not met.

On May 28, 2004, IMI signed an additional marketing agreement with McNeil and completed an exclusive worldwide licensing agreement to sell IMI's skin cholesterol tests. These products are marketed by McNeil and its worldwide affiliates under the brand name PREVU* Skin Sterol Test. This agreement has a minimum term of 10 years. Under the financial terms of the agreement, IMI received a \$3.0 million up front payment and is eligible to receive a series of milestone payments of up to \$15.75 million (in addition to the \$3.3 million from the May 10, 2002 agreement referred to above) in addition to sales and royalties. Since future royalty rates, royalties and milestone payments under this agreement are based on specific sales, regulatory and clinical development targets, IMI is unable at this time to accurately predict the aggregate future payments that could be received under this agreement.

Product Pipeline

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

- Coronary Artery Disease Risk Assessment Technology¹
 - PREVU* Point of Care Skin Sterol Test, which is cleared for sale in Canada, U.S. (CLIA-exempt) and CE-marked in Europe
 - PREVU* Skin Sterol Test LT (lab-processed format), currently in clinical trials
 - PREVU* Skin Sterol Test PT (home, or consumer, format), currently in development

- ColorectAlert™, currently in clinical studies
- LungAlert™, currently in clinical studies
- Breast cancer test, currently in clinical studies

¹*PREVU* POC was formerly known as Cholesterol 1,2,3™

ISO 13488: 1996 Quality System Certification

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

Business Strategy

Identify and Target Significant Markets with Unmet Needs

IMI 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 IMI believes it can successfully develop and bring to market. IMI'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 2002, Cancer Incidence, Mortality and Prevalence Worldwide. International Association for Cancer Research (IARC), Cancer Base No. 5, Version 2.0, IARC Press, Lyon, 2004*).

Ensure a Multiple Product Pipeline

IMI 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. IMI continuously assesses and studies other possible applications of its technologies. In addition, IMI 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

IMI pursues a strategy of building collaborative relationships with leading companies to conduct clinical trials and to assist with the development of its products. IMI 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 IMI 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, IMI gains the benefit of others' expertise, which enhances the ability of IMI to pursue multiple product opportunities.

Establish and Maintain Strong Intellectual Property Portfolio

Patents and other proprietary rights are essential to IMI's business. IMI 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. IMI has acquired, by licence or assignment, rights to patents and applications filed in Canada, the U.S. and internationally. IMI 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

IMI 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 IMI

Industry Overview

The Market for Disease Detection or Biomarkers

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, or approximately 12% of the population, 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, or about 7% of the population at that time. As the people age, the incidence of disease, including cardiovascular disease and cancer, increases.

The aging population has contributed to a dramatic growth in total health care spending. U.S. health care spending is expected to represent 18% of GDP by 2012, up from 15% in 2002 (*U.S. Department of Health and Human Services, as cited in the New York Times, January 9, 2004*).

As a result of 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 IMI 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 (*Theta High Growth Diagnostic Markets, Report No. 1045, Sept. 2000*) 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 IMI anticipates that several of IMI’s products will extend into these new market segments. With its initial products, IMI 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.

Research and Development

Below is a summary of IMI’s products and the related stages of development for each product in clinical development. The summary contains forward-looking statements regarding timing of completion of product development phases. The actual timing of completion of those phases could differ materially from the estimates produced in the table.

PRODUCT	DESCRIPTION	PHASE OF DEVELOPMENT	2004 EXPENSES	NEXT PHASE FOR 2005
Coronary Artery Disease Risk Assessment Technology				
PREVU*POC Skin Sterol Test	Point of care skin cholesterol test that provides information about an individual’s risk of coronary artery disease	Regulatory clearance in Canada, U.S.A. and Europe		Clinical trials for additional regulatory claims; commercial sales
PREVU* Skin Sterol Test LT	Lab-processed skin test	Clinical trials in progress; patent pending		Complete clinical trials; prepare for regulatory submission; commercial launch in select markets

PRODUCT	DESCRIPTION	PHASE OF DEVELOPMENT	2004 EXPENSES	NEXT PHASE FOR 2005
PREVU* Skin Sterol Test PT	Semi-quantitative consumer test	Prototype completed		Initiate pilot clinical trial
Total expenditures on skin cholesterol:			<u>\$1,476,000</u>	
Cancer				
ColorectAlert™ And Colopath™	Mucus test for detection of colorectal cancer	2,000 patients tested in clinical trials	<u>\$ 305,000</u>	Initiate additional clinical trials for regulatory clearance
LungAlert™	Sputum test for detection of lung cancer	Automation of procedures; 1,000 patients tested in clinical trials	<u>\$ 255,000</u>	Publish scientific papers Initiate clinical trials for regulatory clearance
Breast Cancer	Nipple aspirate test for detection of breast cancer	Completed pilot clinical trial	<u>\$ 43,000</u>	Initiate clinical trials for regulatory clearance

Coronary Artery Disease (CAD) Risk Assessment Technology

Coronary artery disease caused by atherosclerosis (the hardening and narrowing of the arteries) remains the number one cause of morbidity and mortality in North America and many other parts of the world. Prevention and intervention require the cost-effective identification of those individuals not only having the disease but also those at risk of developing the disease. A desired goal is a simple and widely available method for identifying high-risk individuals. Therefore, there is currently much interest in determining levels of marker molecules that are able to predict risk of atherosclerotic disease.

Traditionally, methods of blood plasma total cholesterol levels have been widely used to determine risk of atherosclerosis. Cholesterol is a soft, waxy substance that is produced by the body, as well as obtained from eating certain foods, such as meat, eggs, and other animal products. 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 resulting condition is known as an atherosclerotic plaque, which contributes to increased risk for coronary artery disease; angina pectoris and sudden cardiac death; stroke; and peripheral vascular disease.

Plasma total cholesterol levels ("TC") (sometimes referred to as serum lipid levels), alone do not accurately predict risk of atherosclerosis. Better results have been obtained through measurement of plasma lipoproteins. 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"). For example, 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.

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 United States National Cholesterol Education Program ("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 CAD 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.

Although the NCEP ATP III 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.

Additionally, all plasma measurements require blood sampling after a long period of fasting so that dietary cholesterol does not interfere. The sampling is invasive, uncomfortable and carries some small risk of infection. These tests may be highly variable in results over a series of days. Furthermore, analysis of the sample requires complicated and expensive equipment.

In many cases, the levels of plasma cholesterol and lipoproteins do not correlate with the extent of atherosclerotic disease. There is a need for assaying other marker molecules that reflect the extent of atherosclerosis and provide a risk assessment of cardiovascular disease. Significant amounts of cholesterol occur in tissue in addition to the cholesterol found in plasma. Increased levels in tissue have been shown to reflect the presence *and extent* of atherosclerosis.

Market

NIH guidelines provide that individuals (all adults over 20 years of age and children over the age of two with a family history of high total cholesterol or heart disease) with satisfactory total cholesterol values should have their cholesterol tested every five years, individuals with borderline high TC should have a lipid test 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 2005 report by the American Heart Association, in 2002, approximately 107 million Americans adults, representing approximately half the U.S. adult population, had elevated cholesterol levels and more than 38 million American adults had cholesterol readings over the danger level (240 mg/dL or higher). 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 2005 is projected to reach US\$393.5 billion (*American Heart Association, Heart Disease and Stroke Statistics, 2005 Update*).

While blood cholesterol remains an important risk factor for heart disease, it is widely accepted that several risk factors for CAD must be considered to provide an accurate picture of absolute risk of disease. Absolute cardiovascular disease risk is determined by a combination of all cardiovascular risk factors present, and accurate assessment of risk level is key to effective treatment and risk management. Other traditional risk factors include:

- increasing age
- heredity
- tobacco smoking
- high blood pressure
- physical inactivity
- diet
- obesity
- diabetes mellitus

A number of other emerging factors that have demonstrated a link to heart disease include C-reactive protein (CRP), homocysteine, carotid intima-media (CIMT) thickness, electron-beam tomography for coronary calcium, ankle/brachial blood pressure index (ABI), soluble intercellular adhesion molecule ICAM-1, among others.

Many of these factors are costly to measure or assess, are resource intensive and inappropriate for a primary care setting, and require invasive procedures. IMI has developed a more reliable, patient-friendly and cost-effective tool, PREVU* Point of Care (POC) Skin Sterol Test, that assesses patients at high risk of coronary artery disease and can be used to monitor their risk status over time.

The Opportunity

Coronary artery disease is believed to be largely preventable. Most patients who develop CAD have at least one major risk factor that exceeds recommended levels. These higher-risk patients can benefit the most from additional risk stratification testing. Emerging evidence supports the use of non-invasive tests, such as skin sterol, to detect subclinical, or hidden, disease. Identifying patients with high subclinical cardiovascular disease is key to preventing a first cardiac event and reducing the overall burden of heart disease. IMI believes that PREVU* Point of Care Skin Sterol Test is a strong candidate as a tool for risk stratification in the primary, or point of care, prevention of CAD.

Skin Cholesterol Pathology

In 1993 IMI acquired the patent rights underlying IMI'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 IMI - Coronary Artery Disease (CAD) Risk Assessment Technology - Patents".

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.

IMI's Cardiovascular Products

PREVU* POC Skin Sterol Test, formerly known as 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.

PREVU* POC 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 "Business of IMI"), 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 CAD risk.

PREVU* POC has a shelf life of 24 months. Management of IMI believes that this test is inexpensive to produce and will be cost competitive with current alternative tests. PREVU* POC is designed for use at the point of care and is being marketed by McNeil Consumer Healthcare to the professional medical community, including physicians, laboratories, clinics and pharmacies.

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

- PREVU* Skin Sterol Test (LT) is a lab-processed test that is administered painlessly and rapidly, without fasting, needles or blood sample required. The testing procedure samples surface skin cells from the palm of the hand using a specially designed adhesive,

which is then sent to a laboratory where the surface is assessed for skin cholesterol. This test is currently in clinical trials.

- PREVU* Skin Sterol Test (PT) is a single-use, two-minute test designed primarily for home use. It is currently in development with clinical trials expected to start later in 2005.

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 IMI. IMI 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, IMI has a right of first refusal for a license on any intellectual property that is created as a result of the funding. IMI also has the right under this agreement for the use of laboratory facilities at McMaster.

From November 1997 to December 1998, IMI 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).

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. Results from 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 a sub-study at 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 AHA 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 November 2004, IMI announced a multi-center skin sterol study, led by the Montreal Heart Institute. The study will determine whether skin sterol values measured by PREVU* Point of Care Skin Sterol Test are substantially equivalent to skin sterol values as measured by IMI's new lab-processed format of the test, PREVU* Skin Sterol Test LT. The study, to include 600 patients scheduled for coronary angiography and 100 healthy age- and gender-matched controls, will be performed at multiple sites in Canada, including the Montreal Heart Institute. Patients will be tested with both formats of the skin cholesterol test. A fasting serum sample will also be taken and tested for traditional risk factors. Management expects that this new trial, with the inclusion of the lab test, will significantly extend the scientific validation of IMI's skin cholesterol technology to new test formats. Additionally, management of IMI believes the successful completion of this trial will allow for additional product approvals in key markets as well as milestone payments from McNeil.

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

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/PRESENTATIONS
PREVU* Skin Sterol Test: Completed Studies					
Skin sterol and stress test	Dr. Dennis Sprecher	The Cleveland Clinic Foundation	Determine relationship between skin sterol and serum lipid levels; measure correlation of skin sterol to stress test outcome	Skin sterol shown to be an independent predictor of functional CVD as measured by stress test outcome	Presented at American Heart Association (AHA) annual meeting, 2000. Published in <i>Journal of Clinical Chemistry</i> in 2001
Skin sterol and response to therapy	Dr. Dennis Sprecher	The Cleveland Clinic Foundation	Determine ability of skin sterol to monitor patient response to lipid-lowering medications	Data suggested that skin sterol might have utility in monitoring response to cholesterol-lowering therapies	Presented at American Association for Clinical Chemistry annual meeting in 1999
Measuring skin sterol levels to assess CAD	Dr. Dennis Sprecher	The Cleveland Clinic Foundation; The Canadian Heart Research Centre; The Trillium Health Centre	Correlation between skin sterol and angiography outcome	Demonstrated that skin sterol was independently associated with the presence and extent of CAD as determined by angiography, the gold standard for diagnosis of CAD	Presented at AHA's Arteriosclerosis, Thrombosis and Vascular Biology annual meeting in 2002; published in journal <i>Atherosclerosis</i> in 2003
Skin sterol and other markers of CAD risk	Dr. John Mancini	University of British Columbia; St. Paul's Hospital	Determine correlation of skin sterol to other measures of CAD risk, including carotid sonography, flow-mediated brachial vasoactivity and serum markers.	Demonstrated that skin sterol correlates to Framingham Global Risk Score and inflammatory markers, notably ICAM-1	Published in <i>American Journal of Cardiology</i> in 2002
Pediatric skin sterol study	Dr. Katherine Morrison	St. Joseph's Hospital	Examine skin sterol levels in children with hypercholesterolemia	Demonstrated that skin sterol can be reliably measured in children	Presented at the 2003 Endocrine Society Annual Meeting

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
Skin sterol and statins	Dr. Marcus Reiter	University of Vienna	Examining skin sterol response to certain cholesterol-lowering medications	Patients treated with statins experienced decreases in skin sterol values as well as in blood cholesterol; initial data shows that skin sterol may be a useful monitoring tool for patients taking statins	Data published in <i>Journal of Clinical chemistry</i> in January 2005
Skin sterol and carotid IMT	Dr. James Stein	University of Wisconsin	Study measuring relationship between skin sterol and CAD using carotid IMT	Skin sterol has strong correlation to carotid IMT, a well-established risk factor for heart disease	Data presented at American College of Cardiology annual meeting, March 2005.
PREVU* Skin Sterol Test: Ongoing Studies					
ARISE (Aggressive Reduction in Inflammation Stops Events)	Dr. Rob Scott	AtheroGenics, Inc.; study conducted at multiple sites around world	Study will examine skin sterol changes in response to AtheroGenics' AGI-1067 therapy. Trial will also provide data on relationship between skin sterol and primary cardiovascular events		
Correlation study	Dr. Jean-Claude Tardif	Montreal Heart Institute	Data from trial expected to demonstrate that lab-processed format of test, PREVU*LT, correlates to PREVU* POC. Successful completion could lead to regulatory approval and milestone payment from McNeil		

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
Skin sterol and new CAD risk markers (PREVU*POC* and PREVU*PT)	Dr. John Mancini; Dr. Sammy Chan; Dr. Jiri Frolich	University of British Columbia	Study will examine relationship between skin sterol and a variety of new and established cardiovascular risk markers in high-risk patients. It will also examine how skin sterol responds to various therapies		
MESA (Multi-Ethnic Study of Atherosclerosis) sub-study	Dr. Pamela Ouyang	National Heart, Lung and Blood Institute; Johns Hopkins Bayview Medical Center	Study examining correlation of skin sterol to early markers of CAD across different ethnic groups	Interim data demonstrated that skin sterol levels correlated with the presence and extent of coronary calcification	Interim data presented at American Heart Association in 2003
All Comers' study	Dr. Dennis Sprecher	The Cleveland Clinic Foundation	Study examining relationship between skin sterol and Framingham Global Risk Score and other markers of CAD in patients suspected of having CAD. Trial includes PREVU* POC and lab-processed format of test		
PRACTICE	Dr. Milan Gupta	William Osler Health Centre	Examining skin sterol levels in South Asians	Interim data confirmed that skin sterol provides new information about a patient's risk of CAD. Skin sterol may have value in stratifying patients with established CAD who have been treated with cholesterol-lowering medications	Data presented at Canadian Cardiovascular Congress in October 2004

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
WAVE - evaluation of skin sterol levels in patients on warfarin therapy	Dr. Sonia Anand	Canadian Institute for Health Research; conducted at Hamilton General Hospital	Relationship between skin sterol and cardiac events in high-risk patients		
Skin sterol and remnant lipoproteins	Dr. David Waters	University of California at San Francisco	Study examining relationship between skin sterol and lipoprotein sub-fragments		
Skin sterol and LDL - cholesterol particle size	Dr. David Waters	University of California at San Francisco	Study to examine whether skin sterol levels change in response to various therapies		
Skin sterol levels in patients with Type 1 diabetes	Dr. James Stein	University of Wisconsin	Study examining relationship between skin sterol and diabetes, other markers		
Skin sterol response in patients with other diseases	Confidential	Sponsored by corporate partner	Examining response of skin sterol to therapy and correlation with other markers		
PREVU* LT	Dr. Sonia Anand	Hamilton General Hospital	Examining how skin sterol correlates to vascular disease in high-risk patients		
Hypertension study	Dr. Pamela Ouyang	Johns Hopkins	Examining skin sterol changes after therapy in patients with hypertension		
Correlation between PREVU* POC and PREVU* LT	Dr. Lawrence Leiter	St. Michael's Hospital	Comparing skin sterol values generated by PREVU* POC to those obtained by PREVU* LT in patients with two risk factors for CAD but who are not on medication		

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
Skin sterol relationship to various risk factors	Dr. Marcus Reiter	University of Vienna	Examining correlation of skin sterol to various risk factors, including serum lipids, glucose and homocysteine, among others		
Skin sterol and peripheral vascular disease (PVD)	Dr. Marcus Reiter	University of Vienna	Correlation of skin sterol to PVD and significant events		

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, IMI received FDA clearance for sale of Cholesterol 1,2,3 in the United States 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, IMI CE-marked Cholesterol 1,2,3, enabling IMI 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 can follow after translation of the labelling for Cholesterol 1,2,3 in their respective languages has been completed.

Production and Services

On May 14, 1999, IMI 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 IMI 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, IMI has agreed to purchase all of IMI's worldwide requirements for colour measuring devices and related software for use by IMI in marketing and selling Cholesterol 1,2,3 Systems in point-of-care applications. 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. The X-Rite Agreement expires in 2005 and will be renegotiated during the year.

On June 19, 2001, IMI entered into an exclusive agreement with Diagnostic Chemicals Limited ("DCL") to manufacture and supply IMI with Cholesterol 1,2,3 test kits for the U.S. and Canada. The term of the DCL agreement is five years unless earlier terminated by either party upon the material breach by the other party or by IMI with 180 days' notice or by DCL with 12 months' notice.

IMI adheres to Good Manufacturing Practices, or GMP, which is a critical component in ensuring quality. GMP, a universal concept throughout the medical device industry, refers to internationally accepted quality standards for ensuring that products are produced in a consistent and controlled way. GMP regulations are the minimum requirements that must be adhered to when manufacturing, processing, packing, or holding a medical device. Following these regulations gives assurance that the device has the required safety, identity, and quality characteristics.

IMI has established and maintains a quality system to ensure high standards of production and operational quality, and inventory management, which extends to third-party suppliers of components or services. In 2003 IMI received ISO 13488:1996 Quality System Certification from a Canadian Medical Device Conformity Assessment System (CMDCAS)-recognized registrar. This certification, which is a

regulatory requirement in Canada and Europe for new product license submissions, confirms that IMI meets the highest international standards for quality control and customer service.

Marketing and Distribution

On May 10, 2002, IMI entered into an agreement with McNeil Consumer Healthcare (“McNeil”), a Johnson & Johnson company, for the marketing and distribution of IMI’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. IMI subsequently expanded its relationship with McNeil on May 28, 2004, signing an exclusive worldwide licensing agreement for IMI’s skin cholesterol tests. These products are marketed by McNeil and its worldwide affiliates under the brand name PREVU* Skin Sterol Test. See “General Development of the Business of IMI – Key Strategic Relationships.”

In 2004, IMI made initial shipments of PREVU* Skin Sterol Test to McNeil. In the first quarter of 2005, McNeil made PREVU* POC available for sale to medical professionals in North America and select European markets.

Patents

IMI 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 the 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, IMI 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, in the U.S. in 2003, and in China and Europe in 2004. The European patent was granted for 11 European countries, including the United Kingdom. This patent is also pending in Brazil, Japan and Mexico.

In May 1998, IMI acquired the worldwide patent rights for a method for determining skin cholesterol through the use of biosensor devices. In April 2002, IMI was granted this patent in the U.S. It is currently pending in Europe, Canada and Japan. IMI 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 IMI - Patent and Proprietary Protection”.

In April 2004, IMI filed a patent application for its lab-processed skin cholesterol test with the U.S. Patent and Trademark Office (“U.S. PTO”) and the Canadian Intellectual Property Office.

In August 2004, IMI learned that two of its U.S. patents had been listed as abandoned by the United States Patent and Trademark Office for failure to pay maintenance fees. The failure to pay these fees appears to have occurred during the period when management of the files was being transferred between two separate patent agents. IMI and its agents have filed a petition for reinstatement of the patents.

Subsequent to year end, in February 2005 IMI received notice from the U.S. Patent and Trademark Office regarding IMI’s petition. The U.S. PTO identified specific items that IMI should address, specifically regarding the credentials and procedures of IMI’s patent agents and their performance of clerical functions related to the payment of the maintenance fees, and provided a two-month period during which IMI may submit a request for consideration. Until the U.S. PTO grants that petition, IMI’s patent

petitions will be listed as dismissed. This process is ongoing and there can be no assurance that IMI will be successful in having the patents reinstated.

Trademarks

IMI filed a trademark application on February 22, 2000 with respect to Cholesterol 1,2,3 with the U.S. Patent and Trademark Office. IMI 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. As the licensed manufacturer of the PREVU* POC Skin Sterol Test in Canada, IMI applied for and received a Notice of Allowance in August 2004 for the PREVU trademark in Canada.

Competition

The measurement of cholesterol is currently conducted through blood-based analysis. IMI is not aware of any other test currently marketed or in development that non-invasively measures skin cholesterol. IMI is aware that research has been undertaken using other testing approaches that employ body fluids. For example, Nymox Pharmaceutical Corporation is developing technology that uses saliva to determine cholesterol levels. Other researchers are examining testing approaches that employ 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.

IMI 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. IMI's technology is supported by strong scientific validation, including a number of published papers and presentations. This validation could play an important role in enhancing the endorsement and adoption of skin cholesterol testing by the medical community.

Key Markets

IMI 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 PREVU* POC 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. (IMI'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. IMI is currently developing a consumer format of the test, called PREVU* Skin Sterol Test PT.
- **Screening for insurance risk assessment.** The market for insurance testing represents a significant opportunity for the lab-processed format of IMI's predictive heart disease test, PREVU* Skin Sterol Test LT, throughout North America. About 14 million new insurance policies are granted every year, approximately 6.25 million of which include screening performed using oral fluid testing and/or blood.
- **Home testing market.** PREVU* Skin Sterol Test PT 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. 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. The American Cancer Society recommends screening for colorectal cancer beginning at age 50. It is recommended that both men and women should follow one of the following five testing schedules:

- yearly fecal occult blood test (“FOBT”)*
- flexible sigmoidoscopy every five years
- yearly FOBT* plus flexible sigmoidoscopy every five years**
- double contrast barium enema (“DCBE”) every five years
- colonoscopy every 10 years

*For FOBT, the take-home multiple sample method should be used.

**The combination of FOBT and flexible sigmoidoscopy is preferred over either of these two tests alone.

Market

The American Cancer Society projects that in 2005 there will be an estimated 145,290 new cases of colorectal cancer in the U.S. and more than 56,290 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 2005*). The primary risk factor for colorectal cancer is age, with more than 90% of cases diagnosed in individuals over the age of 50. The U.S. Census Bureau estimates that there are approximately 80 million Americans over the age of 50. However, it is estimated that only about half of the people who should be screened for this deadly disease are actually screened. In 2000, 33% of people aged 50 and older had an FOBT within the past two years. In 2000, 39% of people aged 50 and older had ever received a colorectal endoscopy (sigmoidoscopy or colonoscopy) (*National Cancer Institute Cancer Progress Report – 2003 Update*).

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 39% of colorectal cancers are discovered at an early, localized stage, mostly due to low rates of screening (*American Cancer Society, Cancer Facts and Figures, 2005*).

The Opportunity

IMI’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 IMI and the ColorectAlert Inventor, IMI 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, IMI 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"). IMI entered into an agreement with Procyon dated March 19, 2001, as amended, (the "Procyon License Agreement") whereby IMI 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 IMI. 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.

Development History and Clinical Findings

IMI 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, IMI 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.

Production and Services

IMI’s cancer-related technologies are all manufactured (for clinical trial purposes) by IMI itself in its laboratory located at McMaster University Medical Center.

Patents

IMI 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. In April 2004, IMI received notice that the Japan Patent Office granted IMI’s patent application for a screening test for the early detection of colorectal neoplasia. This extends IMI’s patent coverage in Japan while complementing IMI’s existing intellectual property related to ColorectAlert.

Competition

FOBT is the most frequently used screening method for colorectal cancer. 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.

FOBT has sensitivity of approximately 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 single sample, or digital, fecal occult blood test that physicians often use to screen for colorectal cancer has been shown to miss 95% of malignancies and lesions likely to become cancerous (“Accuracy of Screening for Fecal Occult Blood on a Single Stool Sample Obtained by Digital Rectal Examination: A Comparison with Recommended Sampling Practice”, *Annals of Internal Medicine*, January 18, 2005). IMI believes that many physicians are dissatisfied by fecal occult blood testing in general and would prefer to have an improved test.

Double contrast barium enema has a low sensitivity for detecting cancer. The National Polyp Study found that double contrast barium enema detected only 48% of adenomas greater than 1 cm (“How do I Screen for Colorectal Cancer?” Ross, T.M. The Canadian Journal of Diagnostics, October 2003).

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.

Virtual colonoscopy can be done quickly, with no sedation, and at a lower cost than colonoscopy; however, it is not currently included among the tests recommended by the American Cancer Society for early detection of colorectal cancer. At this time there is not solid scientific evidence that it is as effective at finding early cancers compared with currently recommended screening tests.

Management of IMI 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.

In clinical studies to date, ColorectAlert has been shown to detect more than half of early-stage cancers (Duke's A & B stages). It is simple to perform and cost effective relative to other currently available alternatives. Management believes that these attributes represent an important competitive advantage.

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 2005 there will be an estimated 172,570 new cases of lung cancer and an estimated 163,510 lung cancer deaths, representing 28% of all cancer deaths (*American Cancer Society, Cancer Facts and Figures, 2005*). Lung cancer causes more deaths in both North American men and women than any other cancer, with a five-year survival rate for all stages combined of just 15%. Only 16% of lung cancers are diagnosed at an early stage (*American Cancer Society, Cancer Facts and Figures, 2005*). The survival rate is 49% for cases detected when the disease is still localized. Management believes that these statistics clearly demonstrate the urgent 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 IMI - Colorectal Cancer Tests - The Opportunity" for licensing and technology information.

Development History and Clinical Findings

IMI has developed a prototype of the LungAlert technology suitable for clinical evaluation. IMI 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, IMI 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 were presented in May 2004 at the American Thoracic Society International Conference, a premier global forum for physicians.

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

Production and Services

IMI's cancer-related technologies are all manufactured (for clinical trial purposes) by IMI itself in its laboratory located at McMaster University Medical Center.

Patents

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

Competition

To IMI'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 IMI 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*).

Breast Cancer Test

Pathology

Breast cancer is the most frequently diagnosed cancer among women. It is the second leading cause of cancer death in women, after lung cancer (*American Cancer Society, Cancer Facts and Figures, 2005*).

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.

Numerous studies have shown that early detection of breast cancer saves lives and increases treatment options. According to the American Cancer Society, the recent decline in breast cancer mortality has been attributed to the regular use of screening mammography and to improvements in treatments. Mammography, however, has some limitations. It misses some cancers and sometimes leads to unnecessary additional testing in women who do not have breast cancer.

Market

About 211,240 women in the U.S. are expected to be diagnosed with invasive breast cancer in 2005, and about 40,410 women will die from the disease (*American Cancer Society, Cancer Facts and Figures, 2005*). There are slightly over 2 million women living in the U.S. who have been treated for breast cancer. Breast cancer is the second leading cause of death in women, after lung cancer. When breast cancer is found at a localized stage, the five-year survival rate is 98%.

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

IMI'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

IMI has developed a prototype of the breast cancer test suitable for clinical evaluation. IMI 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 and in the American Cancer Society Journal, *Cancer*, in July 2004.

IMI is working to expand clinical data through larger studies.

Production and Services

IMI's cancer-related technologies are all manufactured (for clinical trial purposes) by IMI itself in its laboratory located at McMaster University Medical Center.

Patents

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

Competition

Other companies are developing and/or marketing proteomic- and genomic-based screening tests for cancer using nipple aspirate fluid, including Power3 Medical and Cytoc Corporation. Other screening technologies in the breast cancer risk assessment field include serum screening, serum progression, tissue progression and a variety of imaging technologies to be used as adjuncts to mammography. Given the relatively high cost of such tests, IMI believes that such technologies would likely be complementary rather than competitive to IMI's test.

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, IMI has identified a number of other technologies for evaluation. IMI is currently assessing likely proprietary position and market potential for some of these technologies as well as evaluating the technological and regulatory obstacles that must be overcome with each program.

Patent and Proprietary Protection

IMI 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, IMI will review the patent applications, if any, and examine the patentability of the technology in question. In some cases, IMI 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. IMI has acquired, by licence or assignment, rights in patents and applications filed in Canada, the U.S. and internationally.

IMI retains independent patent counsel where appropriate. Management of IMI 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 IMI 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 IMI will be approved in all countries; (ii) proceedings will not be commenced seeking to challenge IMI 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 IMI will not infringe upon the patents of third parties; or (v) the scope of patents issued to or licensed by IMI will successfully prevent third parties from developing similar and competitive products. It is not possible to predict how any litigation may affect IMI'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 IMI 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 IMI. As the industry expands, and more patents are issued, the risk increases that IMI's processes and products may give rise to claims that they infringe the patents of others. Actions could be brought against IMI 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, IMI 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 IMI 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, IMI'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, IMI 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 IMI is difficult to quantify, management of IMI believes that such patents will afford adequate protection for it to ensure exclusivity in the conduct of its business operations as described herein. IMI 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, IMI requires all employees and consultants to enter into confidentiality agreements with IMI. There can be no assurance, however, that these agreements will provide meaningful protection for IMI'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, IMI's business may be adversely affected by competitors who independently develop substantially equivalent technology.

In August 2004, IMI learned that two of its U.S. patents had been listed as abandoned by the United States Patent and Trademark Office for failure to pay maintenance fees. The failure to pay these fees appears to have occurred during the period when management of the files was being transferred between two separate patent agents. IMI and its agents have filed a petition for reinstatement of the patents. Subsequent to fiscal year end, in February 2005, IMI received notice from the U.S. PTO regarding IMI's petition to accept unavoidably delayed payments of maintenance fees for two U.S. patents related to IMI's skin tissue cholesterol technology. The U.S. PTO has identified specific items that IMI should address and has provided a two-month period during which IMI may submit a request for consideration. Until the U.S. PTO grants that petition, IMI's patent petitions will be listed as dismissed. The process of reinstating the affected U.S. patents could take several months, and there is no assurance that IMI will be successful in having the patents reinstated

IMI'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".

A summary of IMI's portfolio of patents and patents pending is included below:

Coronary Artery Disease (CAD) Risk Assessment Technology

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Method for producing affinity-enzymatic compounds for visual indication of cholesterol on skin surface	Canada	1,335,968	June 20, 1995	June 20, 2012
Granted	Method of producing affinity-enzymatic compounds for the visual detection of cholesterol on the surface of the skin of a patient, based on a detecting agent with an affinity for cholesterol and a visualization agent	Europe Austria Great Britain France Germany Italy Sweden Switzerland	0 338 189	April 24, 1996	January 18, 2009

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Multilayer Analytical Element	Australia	702,663	June 3, 1999	December 14, 2015
		South Korea	235,211	September 21, 1999	December 14, 2015
		United States	6,605,440	August 12, 2003	December 14, 2015
		Canada	2,207,555	February 24, 2004	December 14, 2015
		China	95,197,367.3	June 23, 2004	December 14, 2005
		Europe Belgium Germany Spain France Great Britain Greece Italy Ireland Netherlands Portugal Spain	0797774	November 10, 2004	December 14, 2015
Pending	Multilayer Analytical Element	PCT	CA95/00698	N/A	N/A
		Brazil	PI9510038-5		
		Japan Mexico	HEi-8-517984 974469		
Granted	Method of Determining Skin Tissue Cholesterol	United States	6,365,363	April 2, 2002	January 26, 2018
Pending	Method of Determining Skin Tissue Cholesterol	PCT	RU98/00010	N/A	N/A
		Canada	2281769		
		Brazil	PI9807594-2		
		Europe	98901608.4		
		Japan Hong Kong	10-5396529 00105898.2		

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it pertains to Skin Cholesterol Measurement</i>	PCT Australia Brazil China Europe Russia Hong Kong India Japan	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001-51596.4	N/A	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Skin Cholesterol Measurement</i>	United States	09/830,708	N/A	N/A
Pending	Direct Assay of Cholesterol in Skin Samples	Canada United States	2,465,427 10/835,397	N/A	N/A
Pending	Method and Apparatus for Non-Invasive Measurement of Skin tissue Cholesterol	United States	Number not yet assigned (Filed February 28, 2005)		
Abandoned (petition for reinstatement has been filed)	Method for visual indication of cholesterol on skin surface agents used therefore and methods for producing such agents	United States	5,489,510	February 6, 1996	February 6, 2013
Abandoned (petition for reinstatement has been filed)	Method for producing affino-enzymatic compounds and visualizing agent and application thereof	United States	5,587,295	December 24, 1996	December 24, 2013

ColorectAlert™

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Rectal Mucus Test and Kit for Detecting Cancerous and Precancerous Conditions	USA	5,162,202	November 10, 1992	December 12, 2009
Granted	Screening Test and Kit for Cancerous and Precancerous Conditions	USA	5,348,860	September 20, 1994	October 15, 2011
Granted	Rectal Mucus Test and Kit for Detecting Cancerous and Precancerous Conditions	Japan	2,990,528	October 15, 1999	April 27, 2010
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Cancer Detection</i>	PCT Australia Brazil China Europe Russia Hong Kong India Japan	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Cancer Detection</i>	USA	09/830,708	N/A	N/A

ColoPath™

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Screening Test for the Early Detection of Colorectal Cancer	USA	6,187,591	February 13,2001	March 16, 2019
Granted	Screening Test for the Early Detection of Colorectal Cancer	Australia	766,057	January 29, 2004	November 3, 2019
Pending	Screening Test for the Early Detection of Colorectal Cancer	Canada	2,352,184	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Brazil	PI19915005	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Israel	139545	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Mexico	012243	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Korea	2001-7005707	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	India	INPCT/2001/00591	N/A	N/A
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	USA	5,416,025	May 16, 1995	November 29, 2013
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Europe	0731914	November 23, 1994	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	France	0731914	April 18, 2001	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Spain	ES 2155513	April 18, 2001	November 23, 2014

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Germany	69427131.4	April 18, 2001	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Great Britain	0731914	April 18, 2001	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Italy	0731914	April 18, 2001	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Australia	687,939	March 5, 1998	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	South Africa	94/9290	October 25, 1995	November 23, 2014
Pending	Screening Test for the Early Detection of Colorectal Neoplasia	Canada	2,176,508	N/A	N/A

LungAlert™ and Breast Cancer Test

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Screening Test and Kit for Cancerous and Precancerous Conditions	USA	5,348,860	September 20, 1994	September 20, 2011
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Cancer Detection</i>	PCT Australia Brazil China Europe Russia Hong Kong India Japan	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Cancer Detection</i>	USA	09/830,708	N/A	N/A

Prostate Cancer

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Method for Detecting Prostate Cancer	USA	5,801,004	September 1, 1998	September 1, 2015

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 IMI may: (i) use different technologies or approaches to develop products similar to products which IMI 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 IMI; and (iii) succeed in obtaining regulatory approval of such products before IMI obtains approval of its products. There can be no assurance that IMI's products will compete successfully or that research and development will not render IMI's products obsolete or uneconomical. See "Risk Factors - Competition".

In the long term, IMI 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 IMI cannot guarantee that personnel who are currently working on behalf of IMI 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 IMI 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 IMI manufactures a few components in its own laboratory, most of the raw materials used in the production of IMI's products are generic laboratory materials that are readily available to IMI 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 IMI due to the widely available nature of these raw materials and the relatively small quantities that are used by IMI at any one time.

Regulatory Requirements

IMI is in the process of developing novel diagnostic devices. These devices are regulated differently in each country in which IMI 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 IMI 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.

United States

As the most significant market for IMI's products is in the United States, 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 IMI 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 Regulations”.

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. IMI may encounter difficulties or unanticipated costs in its efforts to secure necessary governmental approval or licences, which could delay or preclude IMI 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 IMI 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 IMI'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.

IMI received HPB clearance for Cholesterol 1,2,3 in 2001, 510(K) clearance from the FDA for Cholesterol 1,2,3 as part of risk assessment for coronary heart disease in persons with a history of myocardial infarction and/or persons suspected of having significant multivessel CAD (>50% stenosis in >1 vessel as defined by coronary angiography) where further diagnostic evaluation is being considered. Cholesterol 1,2,3 was CE-marked on September 5, 2002 for European marketing. IMI's clinical program is ongoing. IMI expects to submit regulatory applications for lab-processed and consumer formats of the skin cholesterol technology upon completion of certain clinical trials. Additionally, IMI expects to undertake new clinical studies to support new regulatory claims for PREVU* POC Skin Sterol Test's use.

IMI's global marketing partner, McNeil Consumer Healthcare, commenced an education and awareness program actively promoted PREVU* Point of Care Skin Sterol Test at major international medical conferences throughout 2004 and made the product available for sale to the professional medical community in North America in early 2005, with additional world markets to follow through 2005 and beyond. The other technologies of IMI 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 IMI has had success in receiving HPB and FDA clearance for Cholesterol 1,2,3, the product testing and approval/clearance process for IMI'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.

Foreign Operations

IMI's wholly-owned subsidiary, IMI International Medical Innovations Inc. (Switzerland), owns non-North American rights to PREVU* Skin Sterol Test and will manage sales of product to McNeil in these territories.

Economic Dependence

For the years ended December 31, 2004 and 2003, 100% of IMI's total revenues were generated from McNeil.

Employees

IMI 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, IMI 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 IMI on an as-needed basis.

RISK FACTORS

Business-Related Risks

IMI has no experience in marketing products. If IMI cannot successfully market and cause acceptance of its products, IMI will be unable to execute its business plan.

IMI has no experience in marketing its products and has developed a strategy to out-license the marketing to one or more partners, such as major diagnostic or pharmaceutical companies. On May 10, 2002, as amended, IMI announced an agreement with McNeil to market and distribute IMI's skin cholesterol tests in Canada and the insurance laboratory field in the United States and Mexico. On May 28, 2004, IMI announced an additional agreement with McNeil for the worldwide marketing rights to the skin cholesterol tests. There can, however, be no assurance that such efforts will be successful. If IMI 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 IMI's products, even if they prove to be safe and effective and are allowed for marketing by the HPB, the FDA and other regulatory authorities. IMI's ability to achieve significant market share for each of its products could be affected by reimbursement difficulties with government agencies and third-party insurers, which could hamper the speed with which IMI's products are adopted by the medical community and by the public. Market penetration of IMI's products will be influenced by factors including the cost-effectiveness and the overall economic benefits that they offer.

If IMI is unable to generate significant revenues and become profitable in the near future, its business could fail.

To date, IMI has not generated significant ongoing revenues to offset its research and development costs and operating costs and accordingly has not made an operating profit. IMI has historically benefited from the inclusion of Canadian federal and provincial refundable scientific investment tax credits ("ITCs") in its annual operating results. To date, IMI has received \$1,876,000 in ITCs. ITCs are tax credits that IMI receives from the Canadian federal and provincial governments as a result of conducting applied scientific research in Canada. There can be no assurance that ITCs will continue to be available to IMI or, if so, at what levels.

In May 2004, IMI licensed the worldwide marketing and distribution rights for its skin cholesterol tests to McNeil. In 2004, IMI recorded initial sales of the PREVU* Skin Sterol Test to McNeil who promoted the test at major medical conferences. However, there is no assurance that sales and license revenues from this agreement will be sufficient to generate a profit for IMI in the near future.

IMI depends on its patents and proprietary technology. If IMI is unable to prevent infringement of its intellectual property or to defend a claim of infringement, its business will be harmed.

IMI'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. IMI has filed patent

applications in the U.S. and other jurisdictions. There can be no assurance that IMI's outstanding patent applications will be allowed, that IMI will gain access to additional proprietary products that are patentable, that issued patents will provide IMI 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 IMI to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of IMI's products or design around the patented products developed by IMI.

IMI 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 IMI or that such licences will be available at all. If IMI 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, IMI could incur substantial costs in defending itself in suits brought against it on such patents or in suits in which IMI attempts to enforce its own patents against other parties. Also, IMI 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 IMI - Patent and Proprietary Protection".

In August 2004, IMI learned that two of its U.S. patents had been listed as abandoned by the United States Patent and Trademark Office for failure to pay maintenance fees. The failure to pay these fees appears to have occurred during the period when management of the files was being transferred between two separate patent agents. IMI and its agents have filed a petition to seek reinstatement of the patents. Subsequent to fiscal year end, in February 2005 IMI received notice from the U.S. PTO regarding IMI's petition to accept unavoidably delayed payments of maintenance fees for two U.S. patents related to IMI's skin tissue cholesterol technology. The U.S. PTO identified specific items that IMI should address and provided a two-month period during which IMI may submit a request for consideration. Until the U.S. PTO grants that petition, IMI's patent petitions will be listed as dismissed. The process of reinstating the affected U.S. patents could take several months, and there is no assurance that IMI will be successful in having the patents reinstated.

The two patents in question are in force in all other jurisdictions. In the U.S., IMI has an additional two patents in force covering other aspects of the technology as well as two patents pending. Consequently, management believes that it would be extremely difficult for a competitor to develop a similar product. However, there can be no assurance that others will not independently develop a similar product. See "Business of IMI – Coronary Artery Disease (CAD) Risk Assessment Technology – Patents; Business of IMI – Patent and Proprietary Protection".

IMI relies on third parties to manufacture some of its products and any delay or mistake on the part of such manufacturers could result in cancelled orders and a loss of revenues for IMI.

IMI relies on third parties to manufacture and formulate some of its products for clinical trials and for eventual commercial sale. Currently, IMI's skin cholesterol products are manufactured by Diagnostic Chemicals Limited (DCL) and Southmedic Inc., while XRite, Inc. supplies the color measurement instrument used in connection with the tests. To date, IMI has not experienced any material problems, such as disruptions of supply, with these manufacturers. IMI's other products, relating to its cancer technologies, are all manufactured (for clinical trial purposes) by IMI itself in its laboratory located at McMaster University Medical Center.

The ability to ensure a continued supply of products on a timely basis is not entirely within IMI's control. If IMI cannot obtain materials in a timely fashion, the progress of its clinical trials and product sales will be negatively affected.

If IMI cannot obtain additional financing required to support business growth, it will be unable to fund its continuing operations in the future.

Management believes that, based on historic cash expenditures and the current expectation of further revenues from product sales and royalties, IMI's existing cash resources together with the investment tax credits receivable of \$389,000 will be sufficient to meet its current operating and capital requirements through at least 2005.

However, IMI's future capital requirements will depend on many factors, including revenue from the successful commercial launch of its products, 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. If additional financing is required, IMI 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, IMI 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 IMI to relinquish rights to certain of its technologies or products. IMI may not be able to raise additional capital if its capital resources are exhausted.

IMI faces potential risks of product liability which may divert funding from ongoing operations and harm operating results.

The sale and use of products under development by IMI entails risk of product liability. IMI has also agreed to indemnify numerous clinical trial sites, including. 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. as well as McNeil under their respective clinical trial and/or marketing agreements for such liability.

IMI maintains product liability insurance relating to the clinical trials that it conducts on its technologies, and believe that such insurance would be reasonably adequate to cover any torts claims that may arise against IMI at present. Upon commercialization of its products, IMI will expand its insurance coverage to include the commercial sale of IMI's products in the relevant territories. In addition, IMI maintains property, commercial general liability and tenant's legal liability insurance.

As IMI 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 IMI. 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 IMI.

If IMI is unable to acquire future technology necessary for its products, it may be unable to commercialize new products.

IMI's business depends on its ability to identify or negotiate the acquisition of or licenses for future technologies. For example, IMI's cancer technologies are the subject of licenses to use the technologies. IMI may not be able to continue to successfully identify, acquire or license technologies in the future to add to its pipeline of products.

The loss of any key employee could impair IMI's ability to execute its business plan.

IMI'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. IMI 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 IMI are affected by a number of influences outside of the control of IMI. The loss of key employees may affect the speed and success of product development.

To date, IMI has not experienced high rates of employee turnover. As an example, IMI's President and Chief Executive Officer, Executive Vice President of Clinical and Regulatory Affairs, Vice President Finance and Chief Financial Officer, and Vice-President, Corporate Development, have been employed by IMI for 12, eight, seven and five years, respectively. While IMI believe that it has been successful to date in employee retention, IMI may not be able to continue to attract and keep key employees.

IMI is exposed to financial market risks such as interest rates and foreign exchange fluctuations.

IMI's cash is invested in short-term, high-grade securities with varying maturities. Since IMI's intention is to hold these securities to maturity, adverse changes in interest rates would not have a material effect on IMI's results of operations.

IMI makes commitments with foreign suppliers for clinical trials and other services. Adverse changes in foreign exchange rates could increase the costs of these services to IMI.

IMI does not anticipate paying dividends on its common shares, which may affect investors who require a certain amount of liquidity on their investment.

IMI does not intend to pay dividends on its common shares in the foreseeable future, and thus the only return on an investment in the common shares will come from an increase, if any, in the price of the common shares. Investors who require dividend income should not depend on or expect to receive dividends on the common shares.

Industry-Related Risks

Intense competition in the diagnostics industry may harm IMI's ability to license and develop its products.

Technological competition in the diagnostics industry is intense. IMI competes with other companies to license and develop products aimed at diagnosing similar conditions. Many of these companies have substantially greater resources than IMI. IMI may not be able to continue to license the technology that it needs to stay competitive. Further, technological developments by others may render IMI's products or technologies non-competitive. See "Business of IMI – Coronary Artery Disease Risk Assessment Technology", "Business of IMI - Colorectal Cancer Tests", "Business of IMI – Lung Cancer Test",

“Business of IMI – Breast Cancer Test”, “Business of IMI - Competition” and “Business of IMI - Patent and Proprietary Protection”.

Any inability by IMI to develop its products and comply with government regulations may hinder or prevent the development and sale of IMI’s products.

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. To achieve profitable operations, IMI, alone or with others, must successfully develop, introduce, secure regulatory clearance for, and market its products. As at the date hereof, only PREVU* Point of Care Skin Sterol Test has received regulatory clearance from the FDA and HPB and is CE marked in Europe.

Securing regulatory clearances for the marketing of diagnostics products from the HPB in Canada and the FDA in the U.S. can be a long and expensive process, which can delay product development. In this regard, IMI has identified a U.S.-based regulatory affairs consultant to advise IMI on its regulatory applications. In order to obtain regulatory approval for a particular product, human clinical trials conducted by IMI must demonstrate that the product is safe for human use and shows efficacy. Unsatisfactory results obtained from a particular study relating to a program may cause IMI to abandon its commitment to that program. No assurances can be provided that any future human trials, if undertaken, will yield favorable results or that regulatory approval will be granted at all. In addition, if IMI obtains regulatory approval for a product it may only be for limited applications, thereby hindering IMI’s ability to widely market a product. Such events would have a material adverse effect on IMI’s sales and profitability.

Rising health care costs may impair IMI’s ability to commercialize its products.

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 in the professional or laboratory market.

Recent policy initiatives in both the U.S. and Canada have advocated broader screening for the risk of cardiovascular disease and cancer. As a result, medical devices for screening and/or risk assessment for these types of disease may face an increased market potential. IMI may need to develop economic studies to demonstrate the cost-effectiveness of its products in identifying the risk of disease at an earlier stage.

IMI’s performance and general market volatility may cause the price of the common shares to decrease.

The common shares are speculative securities. If IMI performs poorly in the marketing, manufacturing or sales of its products, or in other areas of its business as highlighted in this section, that may cause the market price of the common shares to decline. In addition, there can be no assurance that an active trading market for the common shares will be sustained or that the trading price of the common shares will not be subject to significant fluctuations. Accordingly, an 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 the common shares and should consult professional advisers to assess income tax, legal and other aspects of such an investment.

DIVIDEND RECORD AND POLICY

IMI has not declared any dividends on its shares. The board of directors of IMI does not currently anticipate paying any dividends on its shares in the foreseeable future but intends to retain earnings to finance the growth and development of the business of IMI. Any future determination to pay dividends will be at the discretion of the board of directors of IMI and will depend upon IMI's financial condition, results of operations, capital requirements and such other factors as the board of directors of IMI deems relevant.

DESCRIPTION OF SHARE CAPITAL

IMI's authorized capital consists of an unlimited number of common shares (the "Common Shares") and an unlimited number of preferred shares, issuable in series (the "Preferred Shares").

This section is a summary and may not describe every aspect of IMI's authorized capital. IMI's articles and by-laws provide a complete description of the authorized capital and are publicly available on www.sedar.com.

Common Shares

The rights, privileges, restrictions and conditions attaching to the Common Shares are as follows:

- (a) Each holder of Common Shares shall be entitled to receive notice of and to attend all meetings of shareholders of IMI, except meetings at which only holders of other classes or series of shares are entitled to attend, and at all such meetings shall be entitled to one vote in respect of each Common Share held by such holder.
- (b) Subject to the prior rights attaching to other holders of another class of shares, the holders of Common Shares shall be entitled to receive dividends if, as and when declared by the directors.
- (c) In the event of any liquidation, dissolution or winding-up of IMI or other distribution of the assets of IMI among its shareholders for the purpose of winding-up its affairs, the holders of Common Shares shall be entitled, subject to the rights of holders of shares of any class ranking prior to the Common Shares, to receive the remaining property or assets of IMI.

Preferred Shares

Preferred Shares may at any time or from time to time be issued in one or more series. Prior to the issue of the shares of any such series, the directors shall, subject to the limitations set out below, fix the number of shares in, and determine the designation, rights, privileges, restrictions and conditions attaching to the shares of such series.

The Preferred Shares of each series shall, with respect to the payment of dividends and the distribution of assets in the event of the liquidation, dissolution or winding-up of IMI, whether voluntary or involuntary, or any other distribution of the assets of IMI among its shareholders for the purpose of winding up its affairs, rank on a parity with the preferred shares of every other series and be entitled to preference over the Common Shares and the shares of any other class ranking junior to the Preferred Shares. The Preferred Shares of any series shall also be entitled to such other preferences, not inconsistent with these

provisions, over the Common Shares and the shares of any other class ranking junior to the Preferred Shares.

MARKET FOR SECURITIES

Trading Price and Volume

The Common Shares are listed and posted for trading on the Toronto Stock Exchange (“TSX”), where they trade under the stock symbol “IMI”, and on the American Stock Exchange (“Amex”), where they trade under the stock symbol “IME”. The following table sets forth, for the periods indicated, the reported high and low prices and the average volume of trading of the IMI Shares on the TSX and the Amex:

Calendar Period	TSX			Amex		
	High	Low	Average Volume	High	Low	Average Volume
January 2004	\$4.25	\$3.71	9,709	US\$3.30	US\$2.90	3,735
February 2004	\$4.05	\$3.71	13,715	US\$3.06	US\$2.80	2,089
March 2004	\$4.10	\$3.60	6,921	US\$3.05	US\$2.70	2,417
April 2004	\$3.74	\$3.25	10,676	US\$3.07	US\$2.47	1,917
May 2004	\$4.70	\$2.60	31,610	US\$3.40	US\$1.88	6,180
June 2004	\$4.35	\$3.80	17,881	US\$3.25	US\$2.85	4,795
July 2004	\$4.17	\$3.50	11,976	US\$3.20	US\$2.68	3,519
August 2004	\$3.65	\$3.00	7,614	US\$2.73	US\$2.36	1,631
September 2004	\$3.75	\$3.01	8,690	US\$2.84	US\$2.31	4,371
October 2004	\$3.50	\$3.05	8,400	US\$2.77	US\$2.60	1,716
November 2004	\$3.50	\$2.96	8,313	US\$2.83	US\$2.51	7,033
December 2004	\$3.19	\$2.77	12,176	US\$2.55	US\$2.33	4,404

Note:

⁽¹⁾ Source for data in table is the TSX and the Amex.

Prior Sales

IMI has issued Common Shares in the following transactions during the financial year ended December 31, 2004:

1. An aggregate of 1,830 Common Shares were issued to employees and directors under IMI’s share purchase plan for no additional consideration.
2. An aggregate of 35,863 Common Shares were issued to employees, consultants and directors pursuant to the exercise of options under IMI’s incentive stock option plan. The exercise prices of such options ranged from \$2.50 to \$3.45 per share.

DIRECTORS AND EXECUTIVE OFFICERS

Directors and Executive Officers

The following table sets out, for each of IMI's directors and senior executive officers, the person's name, location of residence, position with IMI, if a director, the date on which the person became a director, and principal occupation.

Name and Place of Residence	Position(s) held with IMI	Director Since	Principal Occupation during past five years
John C. Carroll ⁽¹⁾ Ontario, Canada	Director	June 6, 1994	Director of various public companies
Tim Currie Ontario, Canada	Vice President, Corporate Development	n/a	2004 – present: Vice President, Corporate Development of IMI 2000 – 2004: Director, Business Development of IMI
Dr. Michael Evelegh Ontario, Canada	Executive Vice President, Clinical and Regulatory Affairs	n/a	1996 - present: Executive Vice President, Clinical and Regulatory Affairs of IMI
Anthony F. Griffiths ⁽²⁾ Ontario, Canada	Director	July 13, 1995	Director of various public companies
Ronald G. Hosking Ontario, Canada	Vice President, Finance and Chief Financial Officer	n/a	1997 - present: Vice President, Finance and Chief Financial Officer of IMI
Dr. H.B. Brent Norton Ontario, Canada	President, Chief Executive Officer and Director	March 17, 1993	1992 - present: President and Chief Executive Officer of IMI
David A. Rosenkrantz ⁽¹⁾⁽²⁾ Ontario, Canada	Director	June 11, 1998	1997 - present: President and Director of Patica Securities Limited; director of various public companies
Stephen A. Wilgar ⁽¹⁾ Ontario, Canada	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
Ronald D. Henriksen ⁽²⁾ Indiana, U.S.A.	Director	June 16, 2004	Chief Investment Officer, Twilight Ventures, LLC ; director of various public companies

Notes:

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

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

Scientific Advisory Board

IMI 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 IMI pursuant to IMI'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 March 15, 2005, the directors and executive officers of IMI as a group, owned, directly or indirectly, or exercised control or direction over, 4,175,333 Common Shares, representing approximately 19% of the issued and outstanding Common Shares.

Corporate Cease Trade Orders or Bankruptcies

Mr. Anthony Griffiths, a director of IMI, 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 former director of Slater Steel Inc. which was subject to proceedings pursuant to the *Companies Creditors' Arrangement Act*.

Mr. David Rosenkrantz, a director of IMI, 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.

Mr. Henriksen, a director of IMI, was a director of Gliatech, Inc., a U.S. company, from 1997 to 2003 during which time Gliatech, Inc., after withdrawing its primary product from the U.S. market, entered into voluntary bankruptcy proceedings. A final disposition in respect was made by a U.S. court in 2004.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as disclosed below, none of IMI's directors or executive officers, or persons or companies that are the direct or indirect beneficial owners of, or who exercise control or direction over, more than 10% of IMI's outstanding Common Shares, or any associate or affiliate of any of the foregoing, has any interest, direct or indirect, in any material transactions in which IMI has participated during the three financial years ending December 31, 2004 or since January 1, 2005 which has materially affected or will materially affect IMI.

TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for the Common Shares is Equity Transfer Services Inc. at its principal offices in the city of Toronto, Ontario.

MATERIAL CONTRACTS

The following are the contracts that are material to IMI that were entered into either (i) during the year ended December 31, 2004; or (ii) prior to January 1, 2004 that are still in effect, other than contracts entered into in the ordinary course of business:

1. On May 10, 2002 IMI entered into an agreement with McNeil to market and distribute its test for coronary artery disease in Canada. Pursuant to an amendment to this agreement, dated December 20, 2002, McNeil expanded its marketing rights in Canada to include the laboratory field and to extend the territory for the insurance laboratory field to include the United States and Mexico. The amended agreement provides McNeil with exclusive rights, in these fields and in this territory, to the professional skin cholesterol test system and the future version for consumer use, both of which will be jointly developed by McNeil and IMI. The term of the agreement is 15 years and requires McNeil to purchase its skin cholesterol test and to pay ongoing royalties to IMI on sales, in addition to a series of financial milestone payments of up to \$3,300,000, which will be based on McNeil's achievement of specified annual sales levels of the licensed products. IMI may terminate this agreement if certain minimum levels of sales are not met.

On May 28, 2004, IMI completed an exclusive worldwide licensing agreement with McNeil to sell IMI's skin cholesterol tests under the brand name PREVU* Skin Sterol Test, expanding on the two previous agreements. Under the financial terms of the agreement, which has a minimum term of 10 years, IMI received a \$3.0 million upfront payment and can receive a series of additional payments of up to \$15.75 million (over and above the Canadian agreement payments) upon the achievement of specific milestones. In addition to sales of products to McNeil, IMI will also receive royalties on McNeil's sales of the products.

AUDIT COMMITTEE

Audit Committee's Charter

The charter (the "Charter") of IMI's Audit Committee is reproduced as Schedule "A".

Composition of Audit Committee

The Audit Committee is comprised of Mr. John Carroll, Mr. David Rosenkrantz and Mr. Stephen Wilgar. Each member of the Audit Committee is "independent" and "financially literate" (as such terms are defined in Multilateral Instrument 52-110 - Audit Committees ("MI 52-110")).

Relevant Education and Experience

The audit committee of IMI, composed entirely of independent directors, is made up of Stephen A. Wilgar, John C. Carroll and David A. Rosenkrantz. The audit committee has primary responsibility for ensuring the integrity of IMI's financial reporting, risk management and internal controls. The audit committee has unrestricted access to IMI's personnel and documents and has direct communication channels with IMI's external auditors in order to discuss audit and related matters whenever appropriate. The audit committee receives and reviews the annual and financial statements of IMI and makes recommendations thereon to the Board of Directors prior to their approval by the Board of Directors. The audit committee also reviews the scope and planning of the external audit, the form of audit report, and any correspondence from or comments by the external auditors regarding financial reporting and internal controls. Moreover, the audit committee is responsible for correcting weaknesses identified by the external auditors with respect to the internal control systems and for ensuring that the recommended corrections have been implemented.

Mr. David Rosenkrantz serves as the Chair of the Audit Committee. His relevant experience includes, but is not limited to, the following:

- Over 10 years experience in investing as a principal in private companies as Chairman of Patica Corporation, a merchant banking company
- Over seven years experience in investing in, and bringing to the public markets, junior, high-growth companies
- Controlling shareholder of several private corporations
- Chief Compliance Officer of Patica Securities Limited, a Limited Market Dealer in Ontario, as defined and regulated by the Ontario Securities Commission
- Former Chief Compliance Officer for Patica Securities Inc. (now, Kingsdale Capital Markets Inc.), regulated by the Investment Dealers Association and the Ontario Securities Commission, and
- Over 10 years serving as a director on various public company boards, including work chairing and participating on several audit committees

Mr. Wilgar has served as a director of IMI since March 17, 1993. He currently serves as Chairman of AIM Powergen Corp. and Team EMS and is currently a director of Electrohome Ltd. Mr. Wilgar has also served as a director of MedExtra Corp., Dimethaid Research Inc. and Verity International and was the President of SunBlush Technologies Corporation. He also served as President of Warner-Lambert Canada, Asia, Australia and Latin America and is a former President of the Canadian Automobile Association, Central Ontario.

Mr. Carroll has served as a director of IMI since June 6, 1994. Mr. Carroll is a Director of Clairon Holdings and SCOR Reinsurance of Canada. Previously, he was a Director of AXA Assurance Insurance Co. Ltd., Battery Technologies Inc., Quaker Oats of Canada, Scott Paper Limited and Executive Chairman of Molson Breweries of Canada.

Reliance on Certain Exemptions

At no time since the commencement of IMI's most recently completed financial year has IMI relied on any exemption described in items 4, 5 and 6 of Form 52-110F1 under MI 52-110.

Audit Committee Oversight

At no time since the commencement of IMI's most recently completed financial year have any recommendations by the Audit Committee respecting the appointment and/or compensation of IMI's external auditors not been adopted by IMI's board of directors.

Pre-Approval Policies and Procedures

The Charter provides that the Audit Committee must review and approve, in advance, (i) the engagement letters of the external auditor for permissible non-audit services; (ii) the performance, including the fee, scope and timing of any non-audit services provided by the external auditor; and (iii) the nature of and fees for any non-audit services performed by the external auditor and consider whether the nature and extent of such services could detract from the auditor's independence in carrying out the audit function.

External Auditor Service Fees (By Category)

Audit Fees - IMI's external auditors billed IMI approximately \$240,840 and \$111,500 during the financial years ended December 31, 2004 and 2003, respectively, for audit fees. The 2004 amount includes fees related to the unsolicited offer to acquire the shares of IBEX Technologies Inc.

Audit-Related Fees - IMI did not incur any audit-related expenses during the financial years ended December 31, 2004 and 2003 for assurance and related services that are reasonably related to the performance of the audits or reviewing IMI's financial statements and are not included under "Audit Fees" set out above.

Tax Fees - IMI's external auditors billed IMI approximately \$17,300 and \$10,300 during the financial years ended December 31, 2004 and 2003, respectively, for services related to tax compliance, tax advice and tax planning.

All Other Fees - IMI did not incur any other fees during the financial years ended December 31, 2004 and 2003.

ADDITIONAL INFORMATION

Additional information relating to IMI may be found on SEDAR at www.sedar.com.

Additional information relating to IMI, including directors' and officers' remuneration and indebtedness, principal holders of IMI's securities and securities authorized for issuance under equity compensation plans, if applicable, is contained in IMI's management information circular for its recent annual meeting of shareholders.

Additional financial information is provided in IMI's consolidated financial statements for its most recently completed year ended December 31, 2004.

SCHEDULE “A”

AUDIT COMMITTEE CHARTER

1. PURPOSE

The overall purpose of the audit committee (the “Committee”) of the Corporation is to monitor the Corporation’s system of internal financial controls, to evaluate and report on the integrity of the financial statements including the management’s discussion and analysis and related press releases of the Corporation, to enhance the independence of the Corporation’s external auditor and to oversee the accounting and financial reporting processes and audits of financial statements of the Corporation.

2. COMPOSITION, PROCEDURES AND ORGANIZATION

- 2.1 The Committee shall consist of at least three members of the board of directors of the Corporation (the “Board”), each of whom shall be, in the determination of the Board, “independent” as that term is defined by Multilateral Instrument 52-110 - Audit Committees (“MI 52-110”), as amended from time to time. In addition, each member of the Committee shall meet the independence requirements of the American Stock Exchange, as such requirements may be changed from time to time, and of the Sarbanes-Oxley Act of 2002 and the rules issued thereunder. The definition of “independent” for the purposes of MI 52-110 is set out in Exhibit A hereto.
- 2.2 All members of the Committee shall be, in the determination of the Board, “financially literate”, as that term is defined by MI 52-110. The definition of “financially literate” is set out in Exhibit A hereto.
- 2.3 At least 25% of the members of the Committee shall be resident Canadians.
- 2.4 The Board, at its organizational meeting held in conjunction with each annual meeting of shareholders, shall appoint the members of the Committee for the ensuing year or until their resignations or their successors are duly appointed. The Board may at any time remove or replace any member of the Committee and may fill any vacancy in the Committee. Any member of the Committee ceasing to be a director shall cease to be a member of the Committee.
- 2.5 Unless the Board shall have appointed a chair of the Committee, the members of the Committee shall elect a chair from amongst their number.
- 2.6 The Committee shall have access to such officers and employees of the Corporation and to the Corporation’s external auditor and its legal counsel, and to such information respecting the Corporation as it considers necessary or advisable in order to perform its duties.
- 2.7 Notice of meetings may be given to the external auditor, who shall, at the expense of the Corporation, be entitled to attend and to be heard thereat.
- 2.8 Meetings of the Committee shall be conducted as follows:
 - (a) the Committee shall meet at least four times annually or more frequently as circumstances dictate, at such times and at such locations as the chair of the Committee shall determine;

- (b) the external auditor or any member of the Committee may call a meeting of the Committee;
 - (c) any director of the Corporation may request the chair of the Committee to call a meeting of the Committee and may attend such meeting to inform the Committee of a specific matter of concern to such director, and may participate in such meeting to the extent permitted by the chair of the Committee; and
 - (d) the external auditor and management employees shall, when required by the Committee, attend any meeting of the Committee.
- 2.9 The external auditor shall be entitled to communicate directly with the chair of the Committee and may meet separately with the Committee. The Committee, through its chair, may contact directly any employee in the Corporation as it deems necessary, and any employee may bring before the Committee any matter involving questionable, illegal or improper practices or transactions.
- 2.10 Compensation to members of the Committee shall be limited to directors' fees, either in the form of cash or equity, and members shall not accept consulting, advisory or other compensatory fees from the Corporation (other than as members of the Board and Board committee members).
- 2.11 The Committee is authorized, at the Corporation's expense, to retain independent counsel and other advisors as it determines necessary to carry out its duties and to set their compensation.

3. **DUTIES**

- 3.1 The overall duties of the Committee shall be to:
- (a) assist the Board in the discharge of its duties relating to the Corporation's accounting policies and practices, reporting practices and internal controls;
 - (b) establish and maintain a direct line of communication with the Corporation's external auditor and assess its performance;
 - (c) oversee the co-ordination of the activities of the external auditor;
 - (d) ensure that management of the Corporation has designed, implemented and is maintaining an effective system of internal controls;
 - (e) monitor the credibility and objectivity of the Corporation's financial reports;
 - (f) report regularly to the Board on the fulfilment of the Committee's duties;
 - (g) assist the Board in the discharge of its duties relating to the Corporation's compliance with legal and regulatory requirements; and
 - (h) assist the Board in the discharge of its duties relating to risk assessment and risk management.
- 3.2 The Committee shall be directly responsible for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an audit report or performing

other audit, review or attest services for the Corporation, including the resolution of disagreements between management and the external auditor regarding financial reporting, and in carrying out such oversight the Committee's duties shall include:

- (a) recommending to the Board a firm of external auditor to be nominated for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Corporation and recommending the compensation of the external auditor;
- (b) reviewing, where there is to be a change of external auditor, all issues related to the change, including the information to be included in the notice of change of auditor called for under National Instrument 51-102 Continuous Disclosure Obligations, as amended from time to time ("NI 51-102"), and the planned steps for an orderly transition;
- (c) reviewing all reportable events, including disagreements, unresolved issues and consultations, as defined in NI 51-102 on a routine basis, whether or not there is to be a change of external auditor;
- (d) reviewing the engagement letters of the external auditor, both for audit and non-audit services;
- (e) reviewing the performance, including the fee, scope and timing of the audit and other related services and any non-audit services provided by the external auditor; and
- (f) reviewing and approving the nature of and fees for any non-audit services performed for the Corporation by the external auditor and consider whether the nature and extent of such services could detract from the firm's independence in carrying out the audit function.

3.3 The duties of the Committee as they relate to audits and financial reporting shall be to:

- (a) review the audit plan with the external auditor and management;
- (b) review with the external auditor and management any proposed changes in accounting policies, the presentation of the impact of significant risks and uncertainties, and key estimates and judgments of management that may in any such case be material to financial reporting;
- (c) review the contents of the audit report;
- (d) question the external auditor and management regarding significant financial reporting issues discussed during the fiscal period and the method of resolution;
- (e) review the scope and quality of the audit work performed;
- (f) review the adequacy of the Corporation's financial and auditing personnel;
- (g) review the co-operation received by the external auditor from the Corporation's personnel during the audit, any problems encountered by the external auditor and any restrictions on the external auditor's work;

- (h) review the internal resources used;
- (i) review the evaluation of internal controls by the internal auditor (or persons performing the internal audit function) and the external auditor, together with management's response to the recommendations, including subsequent follow-up of any identified weaknesses;
- (j) review the appointments of the chief financial officer, internal auditor (or persons performing the internal audit function) and any key financial executives involved in the financial reporting process;
- (k) review and approve the Corporation's annual audited financial statements and Form 20-F and those of its subsidiaries in conjunction with the report of the external auditor thereon including related management's discussion and analysis and press release, and obtain an explanation from management of all significant variances between comparative reporting periods before release to the public;
- (l) review and approve the Corporation's interim unaudited financial statements and Form 6-K including related management's discussion and analysis and press release and auditors' review thereof, and obtain an explanation from management of all significant variances between comparative reporting periods before release to the public;
- (m) establish a procedure for the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters and employees' confidential anonymous submission of concerns regarding accounting and auditing matters;
- (n) satisfy itself that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, other than the public disclosure referred to in subsection (m) above, and periodically re-assess the adequacy of those controls; and
- (o) review the terms of reference for an internal auditor or internal audit function.

3.4 The duties of the Committee as they relate to accounting and disclosure policies and practices shall be to:

- (a) review the effect of regulatory and accounting initiatives and changes to accounting principles of the Canadian Institute of Chartered Accountants which would have a significant impact on the Corporation's financial reporting as reported to the Committee by management and the external auditor;
- (b) review the appropriateness of the accounting policies used in the preparation of the Corporation's financial statements and consider recommendations for any material change to such policies;
- (c) review the status of material contingent liabilities as reported to the Committee by management;

- (d) review the status of income tax returns and potentially significant tax problems as reported to the Committee by management;
- (e) review any errors or omissions in the current or prior year's financial statements;
- (f) review and approve before their release all public disclosure documents containing audited or unaudited financial information, including all annual and interim earnings press releases, management's discussion and analysis, prospectuses, annual reports to shareholders and annual information forms; and
- (g) oversee and review all financial information and earnings guidance provided to analysts and rating agencies.

3.5 The other duties of the Committee shall include:

- (a) reviewing any inquiries, investigations or audits of a financial nature by governmental, regulatory or taxing authorities;
- (b) formulating clear hiring policies for partners, employees and former partners and employees of the Corporation's present and former external auditor;
- (c) reviewing annual operating and capital budgets;
- (d) reviewing the funding and administration of the Corporation's compensation and pension plans;
- (e) reviewing and reporting to the Board on difficulties and problems with regulatory agencies which are likely to have a significant financial impact;
- (f) inquiring of management and the external auditor as to any activities that may be or may appear to be illegal or unethical; and
- (g) any other questions or matters referred to it by the Board.

EXHIBIT A

AUDIT COMMITTEE CHARTER

Meaning of “**Financially Literate**”:

“**Financially Literate**” means the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Corporation’s financial statements.

Meaning of “**Independence**”:

1. A member of the Committee is independent if he or she has no direct or indirect material relationship with the Corporation.
2. For the purposes of paragraph (1), a “material relationship” is a relationship which could, in the view of the Corporation’s board of directors, be reasonably expected to interfere with the exercise of a member’s independent judgement.
3. Despite paragraph (2), the following individuals are considered to have a material relationship with the Corporation:
 - (a) an individual who is, or has been within the last three years, an employee or executive officer of Corporation;
 - (b) an individual whose immediate family member is, or has been within the last three years, an executive officer of the Corporation;
 - (c) an individual who:
 - (i) is a partner of a firm that is the Corporation’s internal or external auditor,
 - (ii) is an employee of that firm, or
 - (iii) was within the last three years a partner or employee of that firm and personally worked on the Corporation’s audit within that time;
 - (d) an individual whose spouse, minor child or stepchild, or child or stepchild who shares a home with the individual:
 - (i) is a partner of a firm that is the Corporation’s internal or external auditor,
 - (ii) is an employee of that firm and participates in its audit, assurance or tax compliance (but not tax planning) practice, or

- (iii) was within the last three years a partner or employee of that firm and personally worked on the Corporation's audit within that time;
 - (e) an individual who, or whose immediate family member, is or has been within the last three years, an executive officer of an entity if any of the Corporation's current executive officers serves or served at that same time on the entity's compensation committee; and
 - (f) an individual who received, or whose immediate family member who is employed as an executive officer of the Corporation received, more than \$75,000 in direct compensation from the Corporation during any 12 month period within the last three years.
- 4. Despite paragraph (3), an individual will not be considered to have a material relationship with the Corporation solely because he or she had a relationship identified in paragraph (3)(c) if that relationship ended before March 30, 2004.
- 5. For the purposes of paragraphs (3)(c) and (3)(d), a partner does not include a fixed income partner whose interest in the firm that is the internal or external auditor is limited to the receipt of fixed amounts of compensation (including deferred compensation) for prior service with that firm if the compensation is not contingent in any way on continued service.
- 6. For the purposes of paragraph (3)(f), direct compensation does not include:
 - (a) remuneration for acting as a member of the board of directors or of any board committee of the Corporation, and
 - (b) the receipt of fixed amounts of compensation under a retirement plan (including deferred compensation) for prior service with the Corporation if the compensation is not contingent in any way on continued service.
- 7. Despite paragraph (3), an individual will not be considered to have a material relationship with the Corporation solely because the individual or his or her immediate family member
 - (a) has previously acted as an interim chief executive officer of the Corporation, or
 - (b) acts, or has previously acted, as a chair or vice-chair of the board of directors or of any board committee of the Corporation on a part-time basis.
- 8. For the purpose of paragraphs 1 through 7, the Corporation includes a subsidiary entity of the Corporation and a parent of the Corporation.
- 9. Despite any determination made under paragraphs 1 through 7, an individual who
 - (a) has a relationship with the Corporation pursuant to which the individual may accept, directly or indirectly, any consulting, advisory or other compensatory fee from the Corporation or any subsidiary entity of the Corporation, other than as remuneration for acting in his or her capacity as a member of the board of directors or any board committee, or as a part-time chair or vice-chair of the board or any board committee; or

(b) is an affiliated entity of the Corporation or any of its subsidiary entities,

is considered to have a material relationship with the Corporation.

10. For the purposes of paragraph 9, the indirect acceptance by an individual of any consulting, advisory or other compensatory fee includes acceptance of a fee by

(a) an individual's spouse, minor child or stepchild, or a child or stepchild who shares the individual's home; or

(b) an entity in which such individual is a partner, member, an officer such as a managing director occupying a comparable position or executive officer, or occupies a similar position (except limited partners, non-managing members and those occupying similar positions who, in each case, have no active role in providing services to the entity) and which provides accounting, consulting, legal, investment banking or financial advisory services to the Corporation or any subsidiary entity of the Corporation.

11. For the purposes of paragraph 9, compensatory fees do not include the receipt of fixed amounts of compensation under a retirement plan (including deferred compensation) for prior service with the Corporation if the compensation is not contingent in any way on continued service."