

IMI INTERNATIONAL MEDICAL INNOVATIONS INC  
Form 20-F  
June 30, 2005

As filed with the Securities and Exchange Commission on June 29, 2005

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g)  
OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2004

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934  
For the transition period from            to

Commission file number

IMI INTERNATIONAL MEDICAL  
INNOVATIONS INC.  
(Exact name of Registrant as specified in its charter)  
Not Applicable  
(Translation of Registrant's Name into English)  
Canada  
(Jurisdiction of incorporation or organization)  
4211 Yonge Street, Suite 615  
Toronto, Ontario M2P 2A9, Canada  
(Address of principal executive offices)

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Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class  
Common Shares

Name of each exchange on which registered  
The American Stock Exchange and  
The Toronto Stock Exchange

**Securities registered or to be registered pursuant to Section 12(g) of the Act.**

**None.**

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act.**

**None.**

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 21,313,595 as of December 31, 2004.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter periods that the registrant was required to file such reports), and (2) has been subject to such reporting requirements for the past 90 days.

Yes  No  Not  
" applicable

Indicate by check mark which financial statement item the registrant has elected to follow.

Item Item  
17 " 18 x

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(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court.

YesNo

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### **NOTE REGARDING FORWARD-LOOKING STATEMENTS**

The Securities and Exchange Commission encourages companies to disclose forward-looking information so that investors can better understand a company's future prospects and make informed investment decisions. This Annual Report on Form 20-F contains such "forward-looking statements". Words such as "anticipate," "estimate," "expects," "projects," "intends," "plans," "believes" and words and terms of similar substance in connection with any discussion of future operating or financial performance may identify forward-looking statements. All forward-looking statements are management's present expectations of future events and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The factors discussed below under "Risk Factors," among others, could cause actual results to differ materially from those described in the forward-looking statements. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only of the date of this Annual Report. The Corporation is not under any obligation, and expressly disclaims any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to the Corporation or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

**PART I****ITEM 1. Identity of Directors, Senior Management and Advisers.****A. Directors and Senior Management**

Not Applicable.

**B. Advisers**

Not Applicable.

**C. Auditors**

Not Applicable.

**ITEM 2. Offer Statistics and Expected Timetable.**

Not Applicable.

**ITEM 3. Key Information.****Currency and Exchange Rates**

All dollar amounts set forth in this Annual Report are in Canadian dollars, except where otherwise indicated. The following table sets forth (i) the exchange rates for the Canadian dollar, expressed in U.S. dollars, in effect at the end of each of the financial periods indicated; (ii) the average exchange rates based on the last day of each month during such periods; and (iii) the high and low exchange rates during such periods, in each case based on the noon buying rate in New York City for cable transfers in Canadian dollars, as certified for customs purposes by the Federal Reserve Bank of New York. The foreign exchange spot rate as at May 31, 2005 was \$0.7992.

	<b>2004</b>	<b>2003</b>	<b>2002</b>	<b>2001</b>	<b>2000</b>	
Average	0.7682	.7136	.6368	.6457	.6732	
	<b>May-05</b>	<b>Apr-05</b>	<b>Mar-05</b>	<b>Feb-05</b>	<b>Jan-05</b>	<b>Dec-04</b>
Low	0.7872	0.7957	0.8024	0.7960	0.8050	0.8064
High	0.8082	0.8233	0.8321	0.8134	0.8346	0.8434
Average	0.7965	0.8091	0.8224	0.803	0.8165	0.8204

**A. Selected Financial Data**

The following table presents selected financial data of the Corporation. This data is derived from the Corporation's consolidated financial statements and the notes to those statements. You should read this data along with "Operating and Financial Review and Prospects" and the Corporation's consolidated financial statements and the notes to those statements included in this Annual Report. All financial data as of December 31, 2004, December 31, 2003 and December 31, 2002 has been derived from the audited financial statements included in this Annual Report. Financial data as of January 31, 2001 and January 21, 2000 has been derived from audited financial statements not included in this Annual Report.

The Corporation's consolidated financial statements have been prepared in accordance with Canadian generally accepted accounting principles ("Canadian GAAP"), which differs in certain significant respects from United States generally accepted accounting principles ("U.S. GAAP"). A detailed description of the principal differences between Canadian GAAP and U.S. GAAP as they relate to the Corporation and a reconciliation to U.S. GAAP is included in note 9 to the audited consolidated financial statements included in this Annual Report.



	Fiscal Year Ended December 31, 2004	Fiscal Year Ended December 31, 2003	Fiscal Year Ended December 31, 2002	11-month Period Ended December 31, 2001	Fiscal Year Ended January 31, 2001
<b>Canadian GAAP:</b>					
Operating Results Product sales	\$ 183,258	nil	nil	nil	nil
License revenue	\$ 302,080	\$ 16,900	nil	nil	nil
Investment tax credits	\$ 205,000	\$ 223,146	\$ 189,908	\$ 131,000	\$ 115,239
Interest income	\$ 123,626	\$ 258,422	\$ 257,407	\$ 386,580	\$ 522,832
Net loss	\$ 5,568,899	\$ 4,062,711	\$ 4,018,262	\$ 3,245,206	\$ 1,833,205
Net loss per share:					
- basic and diluted loss per share	\$ 0.26	\$ 0.19	\$ 0.20	\$ 0.17	\$ 0.11
Loss from continuing operations per share	\$ 0.26	\$ 0.19	\$ 0.20	\$ 0.17	\$ 0.11

Note:

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

Operating results that would differ under U.S. GAAP are as follows:

	Fiscal Year ended December 31, 2004	Fiscal Year ended December 31, 2003	Fiscal Year ended December 31, 2002
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**U.S. GAAP:**

Operating Results Net loss	\$ 5,478,184	\$ 3,949,318	\$ 4,871,140
Net loss per share:			
- basic and diluted loss per share	\$ 0.26	\$ 0.19	\$ 0.24

	As at December 31, 2004	As at December 31, 2003	As at December 31, 2002	As at December 31, 2001	As at January 31, 2001
<b>Canadian GAAP:</b>					
Financial Position					
Total assets	\$ 6,996,079	\$ 8,074,027	\$ 11,379,383	\$ 9,343,958	\$ 11,097,548
Long-term debt	nil	nil	nil	nil	nil
Shareholders' Equity Total					
shareholders' equity (net assets)	\$ 2,496,842	\$ 7,438,279	\$ 10,689,828	\$ 8,948,696	\$ 10,605,574
Capital stock	\$ 24,192,321	\$ 24,056,853	\$ 23,785,884	\$ 18,212,490	\$ 16,934,162
Weighted average number of common shares outstanding	21,276,497	20,967,677	20,406,733	19,097,390	17,376,342
Cash dividends declared per share	nil	nil	nil	nil	nil

Financial position and shareholders' equity that would differ under U.S. GAAP are as follows:

<b>U.S. GAAP:</b>	<b>As at December 31, 2004</b>	<b>As at December 31, 2003</b>	<b>As at December 31, 2002</b>
<b>Financial Position</b>			
Total assets	\$ 6,633,221	\$ 7,620,454	\$ 10,812,417
Long term debt	nil	nil	nil
Shareholders' Equity Total shareholders' equity (net assets)	\$ 2,133,984	\$ 6,984,706	\$ 10,122,862
Capital stock	\$ 28,924,764	\$ 28,789,296	\$ 28,399,039

**D. Capitalization and Indebtedness**

Not Applicable.

**C. Reasons for the Offer and Use of Proceeds**

Not Applicable.

**D. Risk Factors**

You should consider each of the following factors as well as other information in this Annual Report in evaluating the Corporation's business and its prospects. The risks and uncertainties described below are not the only ones the Corporation faces. Additional risks and uncertainties not presently known to the Corporation or that the Corporation currently considers immaterial may also impair the Corporation's business operations. If any of the following risks actually occur, the Corporation's business and financial results could be harmed and the trading price of the Corporation's common stock could decline. You should also refer to the other information set forth in this Annual Report on Form 20-F, including the Corporation's financial statements and related notes.

**Risks Related to the Corporation's Business**

*The Corporation has no experience in marketing products. If the Corporation cannot successfully market and cause consumer acceptance of the Corporation's products, the Corporation will be unable to execute its business plan.*

The Corporation has no experience in marketing its products and has developed a strategy to out-license the marketing function to one or more partners, such as major diagnostic or pharmaceutical companies. On May 10, 2002, as amended, the Corporation announced an agreement with McNeil Consumer Healthcare, a division of McNeil PDI Inc., a Johnson & Johnson company ("McNeil") to market and distribute the Corporation's skin cholesterol tests, branded as PREVU\* Skin Sterol Test, in Canada and, as subsequently amended on December 20, 2003, the insurance laboratory field in the United States and Mexico. On May 28, 2004, the Corporation announced an additional agreement with McNeil for the worldwide marketing rights to the skin cholesterol tests. There can be no assurance, however, that such efforts will be successful. If the Corporation relies on third parties to market its products, the commercial success of such products may be outside of its control. Moreover, there can be no assurance that providers, payers or patients will accept the Corporation's products, even if they prove to be safe and effective and are allowed for marketing by the Canadian Health Products and Food Protection Branch ("HPB"), the U.S. Food and Drug Administration ("FDA") and other regulatory authorities. The ability of the Corporation 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 the Corporation's products are adopted by the medical community and by the public. Market penetration of the Corporation's products will be influenced by factors including

the cost-effectiveness and the overall economic benefits that they offer.

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*If the Corporation is unable to generate significant revenues and become profitable in the near future, its business will fail.*

To date, the Corporation has not generated significant ongoing revenues to offset its research and development costs and operating costs and accordingly has not made an operating profit. See “Key Information- Selected Financial Data,” “Operating and Financial Review and Prospects” and “Financial Information.” The Corporation has historically benefited from the inclusion of Canadian federal and provincial refundable scientific investment tax credits (“ITCs”) in its annual operating results. To date, the Corporation has received \$1,876,000 in ITCs. ITCs are tax credits that the Corporation receives from the Canadian federal and provincial governments as a result of conducting applied scientific research in Canada. During the years that the Corporation was considered a private company for tax purposes, the ITCs that it received amounted to approximately 30% of the Corporation’s research expenditures. Upon the listing of the Corporation’s common shares on the Toronto Stock Exchange in August 2000, the Corporation became eligible to receive cash refunds of only its provincial tax credits, which currently amount to 7% to 10% of the Corporation’s research expenditures. The remainder counts as a tax credit that can be carried forward and applied against future years’ taxable income. The ITC receivable of approximately \$389,000 as of December 31, 2004, is reported as a separate line item on the Corporation’s financial statements. There can be no assurance that grants and ITCs will continue to be available to the Corporation or, if so, at what levels. Also, the Corporation may never achieve significant revenues or sufficient profitable operations to realize its ITC tax credits that have been carried forward.

In May 2004, the Corporation licensed the worldwide marketing and distribution rights for its skin cholesterol tests to McNeil. In 2004, the Corporation recorded initial sales of the PREVU\* Skin Sterol Test to McNeil, which 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 the Corporation in the near future.

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

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

The Corporation may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under any such patents or proprietary rights will be available on terms acceptable to the Corporation or that such licenses will be available at all. If the Corporation does not obtain such licenses, 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 licenses could be foreclosed. In addition, the Corporation could incur substantial costs in defending itself in suits brought against it on such patents or in suits in which the Corporation attempts to enforce its own patents against other parties. Also, the Corporation could be liable for damages or an accounting of profits if it were unsuccessful in defending itself in a suit for infringement of a patent.

In August 2004, the Corporation learned that two of its U.S. patents related to its skin cholesterol technology had been listed as abandoned by the United States Patent and Trademark Office (“U.S. PTO”) 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. The



Corporation and its agents filed a petition to seek reinstatement of the patents. Subsequent to fiscal year end, in February 2005 the Corporation received notice from the U.S. PTO in which the U.S. PTO identified specific items that the Corporation should address. In response, in June 2005 the Corporation filed a request for consideration. Until the U.S. PTO grants that petition, the Corporation'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 the Corporation will be successful in having the patents reinstated.

The two patents in question are in force in other jurisdictions. In the U.S., the Corporation 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 similar products using this technology. However, there can be no assurance that others will not independently develop a similar products.

*The Corporation 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 the Corporation.*

The Corporation relies on third parties to manufacture and formulate some of its products for clinical trials and for commercial sale. Currently, the Corporation's skin cholesterol products are manufactured by Diagnostic Chemicals Limited (DCL) and Southmedic Inc., while X-Rite, Inc. supplies the color measurement instrument used in connection with the tests. The Corporation's other products, relating to its cancer technologies, are all manufactured for clinical trial purposes by the Corporation 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 the Corporation's control. If the Corporation cannot obtain materials in a timely fashion, the progress of its clinical trials and product sales will be negatively affected.

*If the Corporation cannot obtain the additional financing it needs to support its business growth, the Corporation 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 partnering activities, product sales and royalties, the Corporation'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 until at least 2005.

However, the Corporation's future capital requirements will depend on many factors, including revenue from the 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, the Corporation will consider out-licensing its products under collaborative research and development arrangements, and additional public or private financing (including the issuance of additional equity securities) to fund all or a part of particular programs. There can be no assurance that additional funding will be available or, if available, that it will be available on acceptable terms. If such funding is not available, the Corporation may be forced to reduce or eliminate expenditures relating to specific programs relating to the development, testing, production or marketing of its proposed products, or may have to obtain funds through arrangements with corporate partners that require the Corporation to relinquish rights to certain of its technologies or products. The Corporation may not be able to raise additional capital if its capital resources are exhausted. See "Operating and Financial Review and Prospects."

*The Corporation is exposed to a risk of product liability, which may divert funding from ongoing operations and harm operating results.*

The sale and use of products under development by the Corporation entails risk of product liability. As standard practice, the Corporation has agreed to indemnify numerous clinical trial sites, including The

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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, Montreal Heart Institute, University of Wisconsin Medical School, Johns Hopkins University Medical Center, AtheroGenics, Inc., University of Louisville Research Foundation, and McNeil Consumer Healthcare, under its respective marketing agreements, for such liability.

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

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

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

The Corporation's business depends on its ability to identify and negotiate the acquisition of or licenses for future technologies. For example, the Corporation's cancer technologies are the subject of licenses to use the technologies. The Corporation 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 the Corporation's ability to execute its business plan.*

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

To date, the Corporation has not experienced high rates of employee turnover. As an example, the Corporation'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 the Corporation for 12, eight, seven and five years, respectively. While the Corporation believes that it has been successful to date in employee retention, there is no assurance that the Corporation can continue to attract and keep key employees.

*The Corporation is exposed to financial market risks such as interest rates and foreign exchange fluctuations.*

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



The Corporation 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 the Corporation.

*The Corporation does not anticipate paying dividends on its common shares, which may affect investors who require a certain amount of liquidity on their investments.*

The Corporation 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.

*Investors may encounter difficulties in enforcing civil liabilities against the Corporation in the United States.*

The Corporation is a Canadian corporation and a subsidiary, IMI International Medical Innovations Inc. (Switzerland), is a Swiss corporation. Substantially all of the assets of the Corporation or its subsidiaries are located in either Canada or in Switzerland and similarly, all of the executive officers, a majority of the directors of the Corporation and a majority of the experts named in this Annual Report also reside in Canada. As a result, it may be difficult for an investor to effect service of process within the United States upon the Corporation or its subsidiary, or upon such directors, executive officers and experts. Execution by U.S. courts of any judgment obtained against the Corporation, its subsidiary, or its directors or executive officers or the experts named in this Annual Report in U.S. courts would be limited to the assets of the Corporation or of such persons, as the case may be, in the United States. There is doubt as to the enforceability in Canada or in Switzerland of U.S. judgments or liabilities in original actions in Canadian or Swiss courts predicated solely upon the civil liability provisions of the federal securities laws of the United States.

### **Risks Related to the Corporation's Industry**

*Intense competition in the medical device and diagnostics industry may harm the Corporation's ability to license and develop its products.*

Technological competition in the diagnostics industry is intense. The Corporation competes with other companies to license and develop products aimed at diagnosing similar conditions. Many of these companies have substantially greater resources than the Corporation. The Corporation may not be able to continue to license the technology that it needs to stay competitive. Further, technological developments by others may render the Corporation's products or technologies non-competitive. See "Information on the Corporation - Business Overview."

*Any inability by the Corporation to develop its products and comply with government regulations may hinder or prevent the development and sale of the Corporation'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, the Corporation, 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 (POC) 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 United States can be a long and expensive process, which can delay product development. In this regard, the Corporation has identified a U.S.-based regulatory affairs consultant to advise the Corporation on its regulatory applications. In order to obtain regulatory approval for a particular product, human clinical trials conducted by the Corporation 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 the Corporation 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 regulatory approval for a product is obtained by the Corporation it may be only for limited applications, thereby hindering the ability of the Corporation to widely market the product. Such events would have a material adverse effect on the sales and profitability of the Corporation. See "Information on the Corporation - Business Overview."



*Rising health care costs may impair the ability of the Corporation 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 also must 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 listing in reimbursement schedules can have a dramatic impact on a product's market penetration into the professional or laboratory market.

*The Corporation's performance and general market volatility may cause the price of the common shares to decrease.*

The common shares are speculative securities. If the Corporation 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.

#### **ITEM 4. *Information on the Corporation.***

##### **Trademarks**

Cholesterol 1,2,3™, ColorectAlert™, LungAlert™, ColoPath™, and PREVU (in Canada) are registered trademarks of the Corporation. In addition to these marks, IMI owns pending applications for PreMD. All other trademarks or service marks appearing in this Form 20-F are the trademarks or service marks of the companies that own them.

##### **A. *History and Development of the Corporation***

The Corporation was originally incorporated as IMI Diagnatech Inc. under the Canada Business Corporations Act on November 9, 1992. On November 3, 1997, the Corporation changed its name to its present name of IMI International Medical Innovations Inc. The Corporation was amalgamated with its wholly-owned subsidiary 2860601 Canada Inc. pursuant to the Canada Business Corporations Act on February 1, 1999. The only material subsidiary of the Corporation is its wholly-owned subsidiary, IMI International Medical Innovations Inc. (Switzerland), a corporation incorporated under the laws of Switzerland. The Corporation's head office and principal place of business is located at 4211 Yonge Street, Suite 615, Toronto, Ontario, Canada M2P 2A9, and its telephone number is 416-222-3449.

To the knowledge of management of the Corporation, there have been no indications of any public takeover offers by third parties in respect of its shares or by the Corporation in respect of other companies' shares during the last and current fiscal year.

For information concerning the Corporation's capital expenditures and methods of financing, see "Operating and Financial Review and Prospects."

##### **B. *Business Overview***

The Corporation is a medical device company that licenses and manages the development and commercialization of innovative predictive medicine technologies useful in a variety of medical disorders. The Corporation focuses its efforts on medical conditions where there is a well-defined need for tests to detect serious or life-threatening diseases, particularly cardiovascular disease and cancer, which the Corporation believes it can successfully develop and bring to

market. By focusing on identifying better

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predictors of disease as well as simpler screening methods, the Corporation aims to detect the risk of diseases at the earliest possible stage when they can be more effectively treated, or perhaps prevented altogether.

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

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

The Corporation currently owns patents for a coronary artery disease (CAD) risk assessment technology, which is used to measure skin cholesterol for determining an individual's risk of CAD, and has in-licensed the technologies for tests to detect the presence of a marker intended for use in colorectal, lung, breast and other cancers. In addition, the Corporation has patents and patents pending for color measurement in biological reactions and has a right of first refusal on certain related technologies in the predictive medicine field on research being conducted at McMaster University. The Corporation believes that these innovative technologies will fulfil market needs through their ease-of-use and by contributing to cost-effective patient management.

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

### **Key Strategic Relationships**

A key strategic relationship for the Corporation is with McNeil Consumer Healthcare. On May 10, 2002, the Corporation entered into an agreement with McNeil Consumer Healthcare ("McNeil"), a Johnson & Johnson company, to market and distribute the Corporation's 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 tissue cholesterol test system and the future version for consumer use, both of which will be jointly developed by McNeil and the Corporation. The term of the agreement is 15 years and requires McNeil to purchase a minimum amount of our skin tissue cholesterol test and to pay ongoing royalties to the Corporation 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. The Corporation may terminate this agreement if certain minimum levels of sales are not met.



On May 28, 2004, the Corporation completed an exclusive worldwide licensing agreement with McNeil to sell the Corporation's skin tissue 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, the Corporation received a \$3,000,000 upfront payment and can receive a series of additional payments of up to \$15,750,000 (over and above the Canadian agreement payments) upon the achievement of specific milestones. In addition to sales of products to McNeil, the Corporation will also receive royalties on McNeil's sales of the products.

Subsequent to year end, in early fiscal 2005, the Corporation announced that PREVU\* Point of Care Skin Sterol Test is now available for sale to medical professionals in North America and select European markets.

## Product Pipeline

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

- Coronary Artery Disease Risk Assessment Technology
- PREVU\* Point of Care Skin Sterol Test, which is cleared for sale in Canada, U.S. (CLIA-exempt) and CE-marked in Europe<sup>1</sup>
  - PREVU\* LT Skin Sterol Test (lab-processed format), currently in clinical trials
  - PREVU\* PT Skin Sterol Test (home, or consumer, format), currently in development
    - ColorectAlert™, currently in clinical studies
    - LungAlert™, currently in clinical studies
    - Breast cancer test, currently in clinical studies

<sup>1</sup>\*PREVU\* POC was formerly known as Cholesterol 1,2,3™

## ISO 13488: 1996 Quality System Certification

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

## Business Strategy

### *Identify and Target Significant Markets with Unmet Needs*

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

The Corporation builds and maintains a portfolio of products at different stages, which helps to mitigate risk while enhancing opportunities to generate value for stakeholders. The Corporation continuously assesses and studies other



possible applications of its technologies. In addition, the Corporation continues

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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 that are currently available.

#### *Pursue Strategic Relationships*

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

#### *Establish and Maintain Strong Intellectual Property Portfolio*

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

#### *Leverage Management's Scientific, Product Development and Commercialization Expertise*

The Corporation is led by an experienced group of individuals with significant industry expertise in the areas of research, regulatory affairs, business development and finance.

### **Industry Overview**

#### *The Market for Diagnostics*

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

The aging population has 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 these increasing expenditures, cost containment strategies are being evaluated and implemented by governments and private payers around the world. Management has developed and 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 of disease and the initiation of therapy or prevention at an earlier stage in the healthcare process. Management believes that point-of-care or self-testing is optimal because it permits immediate feedback to the patient or medical practitioner, rather than requiring additional and delayed patient contact to provide and explain results. It also reduces the need for costly return visits to the doctor and avoids the expense of specimen collection, preservation, transportation, processing and results reporting by

laboratories. In some cases, hospitals,

health maintenance organizations (“HMOs”), health departments and corporations view screening as an effective way to reduce overall medical costs. As a result, the use of screening and monitoring diagnostics for early intervention, improved treatment and monitoring is becoming an important component of managed health care. This trend toward greater use of point-of-care and self-diagnosis began in the early 1980s and is expected to continue. Examples of such tests include those for cholesterol, glucose, pregnancy, ovulation and various urine components. Management believes that the factors discussed above will lead to increases in the use of devices of the type that the Corporation currently intends to commercialize.

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

#### *The Point-of-Care Market*

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

#### *The Home Testing Market*

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

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

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

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



### *Channels of Distribution*

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

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

### **Coronary Artery Disease (CAD) Risk Assessment Technology**

#### *Skin Cholesterol Pathology*

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 at risk of having 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 measuring blood 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 with the test results. 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 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:

- gender
- increasing age
- heredity
- tobacco smoking
- high blood pressure



- physical inactivity

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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. The Corporation has developed a more reliable, patient-friendly and cost-effective tool, PREVU\* Point of Care (POC) Skin Sterol Test, that assesses patients at risk of coronary artery disease.

### *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. The Corporation believes that PREVU\* Point of Care Skin Sterol Test is a strong candidate as a tool for risk stratification in the primary prevention of CAD. See “Information on the Corporation - Business Overview - Coronary Artery Disease (CAD) Risk Assessment Technology -Patents”.

### *Skin Cholesterol Pathology*

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. 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 cholesterol testing. A number of studies carried out in the 1970s and early 1980s, largely in Europe, have provided evidence in support of this hypothesis. The results of these studies indicate that:

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

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

### *The Corporation’s Cardiovascular Products*

PREVU\* POC Skin Sterol Test, formerly known as Cholesterol 1,2,3<sup>TM</sup>, 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 colorless 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 color change reaction is created. After only two minutes, a hand-held color measurement instrument reads this reaction and produces a quantitative result.

PREVU\* POC is currently packaged in a 20-test kit that contains three dropper bottles consisting of a binding solution, an indicator solution and a positive control, as well as 20 adhesive-backed pads. In addition, a patented hand-held instrument (see "Coronary Artery Disease Risk Assessment Technology - Development History and Clinical Findings"), which connects to a computer is used to measure the color 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 the Corporation 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 made available by McNeil Consumer Healthcare to the professional medical community, including physicians, laboratories, clinics and pharmacies in North America and select European markets.

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

PREVU\* LT Skin Sterol Test 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 using the same reagents and color measurement technology. This test is currently patent pending and in clinical trials.

PREVU\* PT Skin Sterol Test 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 the Corporation. The Corporation provides research and development sponsorship funding to McMaster, which funding commenced in November 2000 and will continue until October 31, 2005. In consideration for this sponsorship, the Corporation has a right of first refusal for a license on any intellectual property that is created as a result of the funding. The Corporation also has the right under this agreement for the use of laboratory facilities at McMaster.

From November 1997 to December 1998, the Corporation conducted a clinical trial at The Cleveland Clinic Foundation (the "Cleveland Clinic"), Preventive Cardiology and Rehabilitation Section, with Dr. Dennis Sprecher as principal investigator. The main objective of this primary study was to evaluate Cholesterol 1,2,3's ability to assess the risk that a person has cardiovascular disease by:

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

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



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

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

A follow-on clinical study to determine the effectiveness of measuring skin cholesterol levels to assess CAD was undertaken at The Canadian Heart Research Centre, The Trillium Health Centre and the Cleveland Clinic, with Dr. Dennis Sprecher acting as the principal investigator. The study measured skin cholesterol levels in 649 patients with the resulting values being compared to angiography. Interim results were presented at the American Heart Association’s (“AHA”) Scientific Sessions, New Orleans in November 2000. Final 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. The results from this trial, published in the June 2002 issue of the American Journal of Cardiology, showed that skin cholesterol was correlated with Framingham global risk and inflammatory markers, notably ICAM-1.

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

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

In November 2004, the Corporation 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 the 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 the Corporation’s skin cholesterol technology to new test formats.

Additionally,

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management of the Corporation believes the successful completion of this trial will allow for additional product approvals in key markets as well as milestone payments from McNeil.

Subsequent to fiscal year end, in May 2005 IMI announced a major clinical study in the life insurance testing industry using PREVU\* LT Skin Sterol Test. The study, called PREPARE (PREVU\* Predicts Atherosclerosis Risk and Events) is intended to confirm the viability of PREVU\* LT in the insurance testing market. The clinical trial will include approximately 25,000 participants in the United States and will be conducted with the participation of certain U.S. life insurers. PREVU\* LT will be performed on applicants for life insurance coverage who agree to participate in the study and compared with traditional risk assessment measures, including high sensitivity c-reactive protein (CRP). Test results will be collected and analyzed by LabOne, Inc. Data from the study will determine the correlation between PREVU\* LT and Framingham Global Risk Score, a traditional method for evaluating the risk of coronary artery disease. Previously published and presented data on PREVU\* POC has shown that skin sterol correlates with Framingham Global Risk Score. In addition, skin sterol has shown to be an independent risk factor for coronary artery disease as defined by angiography, coronary calcium, carotid intima-media thickness and stress test. Studies with PREVU\* LT to date show that skin sterol values as measured by PREVU\* LT correlate to skin sterol values as measured by PREVU\* POC. Management of the Corporation 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 key development and clinical evaluations of PREVU\* to date:

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
<b><i>PREVU* Skin Sterol Test: Completed Studies</i></b>					
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 31st Annual Oak Ridge Conference, 1999. 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 American Heart Association (AHA) annual meeting, 2000. 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	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

sonography,  
flow-mediated  
brachial  
vasoactivity and  
serum markers.

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/PRESENTATIONS
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
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
PREPARE study	Dr. David Waters; Dr. Dennis Sprecher; Dr. John Mancini	Various	Relationship between skin sterol (PREVU*LT) and risk of CVD as estimated by Framingham score		
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. 2004 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
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		

DESCRIPTION	INVESTIGATOR	PRIMARY STUDY SITE	OBJECTIVES	OUTCOME	PUBLICATIONS/ PRESENTATIONS
Correlation between PREVU* POC & PREVU* LT	Dr. Lawrence Leiter	St. Michael's Hospital	Comparing skin sterol values generated by PREVU* POC to those obtained by PREVU* LT in a high-risk population		
Hypertension study	Dr. Pamela Ouyang	Johns Hopkins	Examining skin sterol changes after therapy in patients with hypertension		

### *Regulatory Clearance*

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

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

On September 5, 2002, the Corporation CE-marked Cholesterol 1,2,3, enabling the Corporation to sell this product in Europe as part of a risk assessment for coronary artery disease. The product was registered with the Competent Authority in the U.K. Registrations with Competent Authorities of other European Union Member States 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, the Corporation entered into a six-year supply agreement (the "X-Rite Agreement") with X-Rite, Inc. ("X-Rite"), a Michigan based corporation, under which X-Rite agreed to develop and supply the Corporation with a hand-held instrument (the "X-Rite Instrument") and related software for skin cholesterol testing in a professional setting. The X-Rite Instrument measures the color of the reagents on the palm of the hand and provides a quantitative skin cholesterol result. The X-Rite Agreement expired in May 2005 but the Corporation will continue to order instruments from X-Rite as required. In 2005, the Corporation began development of a next-generation hand-held spectrophotometer that does not require a computer.

On June 19, 2001, the Corporation entered into an exclusive agreement with Diagnostic Chemicals Limited ("DCL") to manufacture and supply the Corporation 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 the Corporation with 180 days' notice or by DCL with 12 months' notice.

The Corporation 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.

The Corporation 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 the Corporation 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 the Corporation meets the highest international standards for quality control and customer service.

### *Marketing and Distribution*

On May 10, 2002, the Corporation entered into an agreement with McNeil Consumer Healthcare ("McNeil"), a Johnson & Johnson company, for the marketing and distribution of the Corporation's skin cholesterol tests for coronary artery



disease in Canada. This agreement was amended on December 20, 2002 to include the laboratory field and to extend the territory for the insurance testing market to include the United States and Mexico. The Corporation subsequently expanded its relationship with McNeil on May 28, 2004, signing an exclusive worldwide

licensing agreement for the Corporation's skin cholesterol tests. These products are marketed by McNeil and its worldwide affiliates under the brand name PREVU\* Skin Sterol Test.

In 2004, the Corporation 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*

The Corporation has obtained patents that cover the chemical formulations for the reagents employed in skin cholesterol testing as well as a method of using the same reagents for the visual indication of cholesterol on 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, the Corporation has received a positive response from the International Preliminary Examining Authority with respect to the patentability of such an analytical element, and, in fact, a patent was granted in both Australia and Korea in 1999, in the U.S. in 2003, in China and Europe in 2004, and in Mexico in 2005. The European patent was granted for 11 European countries, including the United Kingdom. This patent is also pending in Brazil and Japan.

In May 1998, the Corporation acquired the worldwide patent rights for a method for determining skin cholesterol through the use of biosensor devices. In April 2002, the Corporation was granted this patent in the U.S. It was allowed in Canada and Japan in June 2005 and is currently pending in Europe. The Corporation has filed a patent application with regards to the use of spectrophotometric measurement in color-based biochemical and immunological assays. This patent was filed on a worldwide basis. See "Information on the Corporation - Business Overview - Patent and Proprietary Protection".

In April 2004, the Corporation 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, the Corporation learned that two of its U.S. patents for its skin cholesterol technology 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. The Corporation and its agents have filed a petition for reinstatement of the patents.

Subsequent to year end, in February 2005 the Corporation received notice from the U.S. PTO regarding the Corporation's petition. The U.S. PTO identified specific items that the Corporation should address, specifically regarding the credentials and procedures of the Corporation's patent agents and their performance of clerical functions related to the payment of the maintenance fees. In response, in June 2005 the Corporation submitted a request for reconsideration. Until the U.S. PTO grants that petition, the Corporation's patent petitions will be listed as dismissed. This process is ongoing and there can be no assurance that the Corporation will be successful in having the patents reinstated.

### *Trademarks*

The Corporation filed a trademark application on February 22, 2000 with respect to Cholesterol 1,2,3 with the U.S. Patent and Trademark Office. The Corporation received the Notice of Allowance on January 31, 2003. The Cholesterol 1,2,3 trademark has been granted in Canada as well as in Europe. As the licensed manufacturer of the PREVU\* POC Skin Sterol Test in Canada, the Corporation 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. The Corporation is not aware of any other test currently marketed or in development that non-invasively measures skin cholesterol. The Corporation is aware that research has been undertaken using other testing approaches that employ body fluids. 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 “Key Information - Risk Factors”.

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

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

### *Key Markets*

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

***Physician’s office.*** The non-invasive, cost effective and easy-to-use skin cholesterol test 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.

***Pharmacy market.*** Tests may be offered through retail pharmacies to consumers. As well, pharmaceutical companies might be interested in using or co-marketing the tests at the pharmacy level as a means of encouraging individuals to see their doctors for cholesterol lowering drug therapies. The Corporation is currently developing a consumer format of the test, called PREVU\* PT Skin Sterol Test.

***Screening for insurance risk assessment.*** The market for insurance testing represents a significant opportunity for the lab-processed format of the Corporation’s predictive heart disease test, PREVU\* LT Skin Sterol Test, 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

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self-test market is projected to grow from about US\$30 million in 2003 to just under

25

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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*)

**Monitoring for drug and dietary therapy.** Given the ease of use of skin cholesterol testing, the test may be used to monitor the progress of therapy. Thus, pharmaceutical companies may be interested in using or co-marketing this test to ensure patient compliance. The Corporation's skin cholesterol test is not yet cleared for this use.

### **Colorectal Cancer Tests (ColorectAlert and ColoPath)**

#### *Pathology*

Colon and rectal cancer is the third most prevalent cancer in North America and the second most common cause of death due to cancer. Colorectal cancer begins as a benign polyp that subsequently evolves into a malignant lesion. The cancer becomes invasive when it penetrates the wall of the colon or rectum. The cancer may spread 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*

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

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

### *The Technologies*

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





### *Development History and Clinical Findings*

The Corporation has conducted clinical trials to validate the ColorectAlert Inventor's data that had been collected on a few thousand patients. In accordance with a sponsored research agreement (the "St. Michael's Agreement") dated November 30, 1998, the Corporation completed a prospective clinical trial in December 1999 at St. Michael's Hospital ("St. Michael's"), Wellesley Central Site, Toronto, Ontario, Canada with Dr. Norman Marcon as principal investigator. The clinical trial examined ColorectAlert to determine its added benefit, relative to FOBT and CEA, (described below), 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. In addition all patients also underwent a colonoscopy, allowing for further correlation between ColorectAlert values and colonoscopy results. Prior to entering this study, all of these patients had been scheduled for colonoscopy, but for various reasons including having symptoms, 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*

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

### *Patents*

The Corporation acquired the rights to two U.S. patents and one Japanese patent for ColorectAlert as well as the rights to worldwide granted patents and patent applications for ColoPath. A patent involving the spectrophotometric measurement of color-based biochemical and immunological assays has been filed, on a worldwide basis, and is applicable to these technologies. In April 2004, the Corporation received notice that the Japan Patent Office granted the Corporation's patent application for a screening test for the early detection of colorectal neoplasia. This extends the Corporation's patent coverage in Japan, which is a major market, while complementing the Corporation's existing intellectual property related to ColorectAlert and ColoPath.

### *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 30% 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). The Corporation 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 the Corporation is aware of other diagnostic tests under development that may be useful for the detection of all colorectal pathology and is currently monitoring their progress. Some of the firms involved in the development or marketing of such products include Enterix Inc., EXACT Sciences Corporation and E-Z-EM Inc.

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-\$1,000 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 "Information on the Corporation - Business Overview - Colorectal Cancer Tests - The Opportunity" for licensing and technology information.

#### *Development History and Clinical Findings*

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

In accordance with a sponsored research agreement (the "St. Joseph's Agreement") dated January 25, 2002, the Corporation began a prospective clinical trial involving 500 patients at St. Joseph's Hospital ("St. Joseph") and McMaster University, Hamilton, Ontario, Canada 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, the Corporation 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, Canada led by principal investigator Dr. Heidi Roberts.

As part of the study, 1,000 high-risk patients will undergo low-dose spiral 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*

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

#### *Patents*

Patent coverage for LungAlert is the same as patent coverage for ColorectAlert. See "Information on the Corporation - Business Overview - Colorectal Cancer Tests - Patents".

#### *Competition*

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

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

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

#### *Key Markets*

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

### **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*

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

### *Development History and Clinical Findings*

The Corporation has developed a prototype of the breast cancer test suitable for clinical evaluation. The Corporation has tested a small number of samples 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. The Corporation is working to expand clinical data through larger studies.

Subsequent to fiscal year end, in May 2005 the Corporation announced the launch of a pivotal clinical study for its non-invasive breast cancer detection test, in collaboration with the University of Louisville, in Louisville, Kentucky. The 78-patient study will examine nipple aspirate fluid (NAF) from three different female populations: women with no history of breast cancer; women who have a core biopsy-confirmed unilateral ductal carcinoma in situ; and women who have a core biopsy-confirmed unilateral invasive breast cancer. The study will take place at the University of Louisville Hospital, Norton Healthcare facilities and the University of Louisville's James Graham Brown Cancer Center.

### *Production and Services*

The Corporation's cancer-related technologies are all manufactured (for clinical trial purposes) by the Corporation 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 "Information on the Corporation - Business Overview - Colorectal Cancer Test - Patents".

### *Competition*

Mammography is the biggest competition for the Corporation's breast cancer test. It is estimated that there are approximately 48 million mammograms performed each year in the United States. There is currently a debate on the benefit of the test (*Breast Cancer: Facts and Figures 2001-2002*).

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, the Corporation believes that such technologies would likely be complementary rather than competitive to the Corporation's test.

The FDA has cleared two serum cancer markers for use in Breast Cancer Detection. These are CA 27.29 (Truquant BR) and CA 15.3. The FDA has also cleared genetic tests for BRCA1 and HER2.

### *Key Markets*

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

## Other Product Development Programs

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

## Patent and Proprietary Protection

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

### Patents and Patent Applications

#### *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	2004	December 14, 2015
		Europe	0797774	June 23, 2004	December 14, 2015
		Belgium		November 10, 2004	December 14, 2015
		Germany			December 14, 2015
		Spain			December 14, 2015
		France			December 14, 2015
		Great Britain			December 14, 2015
		Greece			December 14, 2015
		Italy			December 14, 2015
		Ireland	974469		December 14, 2015
		Netherlands			December 14, 2015
Portugal			December 14, 2015		
Sweden		April 15, 2005	December 14, 2015		
Mexico			December 14, 2015		
Pending	Multilayer Analytical Element	PCT	CA95/00698	N/A	N/A
		Brazil	PI9510038-5		
		Japan	HEi-8-517984		
		Mexico	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	Accepted in	N/A
		Canada	2281769	Canada June 8, 2005	
		Brazil	PI9807594-2	2005	
		Europe	98901608.4	Accepted in	
		Japan	10-5396529	Japan	
		Hong Kong	00105898.2	May 31, 2005	

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 781034 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001-51596.4	N/A Accepted in Australia March 10, 2005	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Skin Cholesterol Measurement</i>	United States  Continuation in part	09/830,708  10/877,737	N/A	N/A
Pending	Direct Assay of Cholesterol in Skin Samples	Canada (PCT filed in place of Canada)  United States Continuation in part	2,465,427 PCT/CA2005/00642  10/835,397 Number not yet assigned (Filed April 28,2005)	N/A	N/A
Pending	Direct Assay of Skin Protein in Skin Samples Removed by Tape Stripping	United States	Number not yet assigned (Filed May 20, 2005)	N/A	N/A
Pending	Method and Apparatus for Non-Invasive Measurement of Skin tissue Cholesterol	United States	60/656,381	N/A	N/A
Abandoned(petition for reinstatement has been filed)	Method for visual indication of cholesterol on skin	United States	5,489,510	February 6, 1996	February 6, 2013

surface agents used  
therefore and  
methods for  
producing such  
agents

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
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 781034 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A Accepted in Australia March 10, 2005	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays	USA  Continuation in part	09/830,708  10/877,757	N/A	N/A

*As it Pertains to  
Cancer Detection*

**ColoPath™**

<b>Patent Status</b>	<b>Title</b>	<b>Jurisdiction</b>	<b>Patent Number</b>	<b>Grant Date</b>	<b>Expiry Date</b>
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	India	INPCT/2001/00591	N/A	N/A

Cancer

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	October 15, 2011
Pending		PCT	PCT/CA00/00918	N/A	N/A



Spectrophotometric	Australia	781034	Accepted in
Measurement in	Brazil	PI0013096.6	Australia March
Colour-Based	China	00813497.9	10, 2005
Biochemical and	Europe	00954181.4	
Immunological	Russia	RU 2002103517	
Assays	Hong Kong	0310671.6	
	India	PCT/2002/00307	
<i>As it Pertains to</i>	Japan	2001 515964	
<i>Cancer</i>			
<i>Detection</i>			

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays	USA	09/830,708	N/A	N/A
		Continuation in part	10/877,737		
	<i>As it Pertains to Cancer Detection</i>				

*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

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

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

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

Issues may arise with respect to claims of others to rights in the patents or patent applications owned by or licensed to the Corporation. As the industry expands, and more patents are issued, the risk increases that the Corporation's processes and products may give rise to claims that they infringe the patents of others. Actions could be brought against the Corporation or its commercial partners claiming damages or an accounting of profits and seeking to enjoin

them from clinically testing, manufacturing and marketing the affected product or process. If any such action were successful, in addition to any potential liability for damages, the Corporation or its commercial partners could be required to obtain a license in order to continue to manufacture or market the affected product or use the affected process. There can be no assurance that the Corporation or its commercial partners could prevail in any such action or that any license required under any such patent would be made available or, if available, would be available on acceptable terms. If no license is available, the Corporation's ability to commercialize its products may be negatively affected. There may be significant litigation in the industry regarding patents and other intellectual property rights and such litigation could consume substantial resources. If required, the Corporation may seek to

negotiate licenses under competitive or blocking patents that it believes are required for it to commercialize its products.

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

In August 2004, the Corporation learned that two of its U.S. patents relating to its skin cholesterol technology 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. The Corporation and its agents have filed a petition for reinstatement of the patents. Subsequent to fiscal year end, in February 2005, the Corporation received notice from the U.S. PTO regarding the Corporation's petition to accept unavoidably delayed payments of maintenance fees for two U.S. patents related to the Corporation's skin tissue cholesterol technology. The U.S. PTO identified specific items that the Corporation should address. In response, in June 2005 the Corporation submitted a request for reconsideration. Until the U.S. PTO grants that petition, the Corporation'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 the Corporation will be successful in having the patents reinstated.

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

## **Competition**

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

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

Competitors of the Corporation may: (i) use different technologies or approaches to develop products similar to products which the Corporation is seeking to develop; (ii) develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any developed by the Corporation; and (iii) succeed in obtaining regulatory approval of such products before the Corporation obtains approval of its products.

There can be no assurance that the Corporation's products will compete successfully or that research and

development will not render the Corporation's products obsolete or uneconomical. See "Key Information - Risk Factors - Competition".

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

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

### **Raw Materials**

Although the Corporation manufactures a few components in its own laboratory, most of the raw materials used in the production of the Corporation's products are generic laboratory materials that are readily available to the Corporation from commercial sources. The prices of these various materials have remained stable over the past five years. Any volatility in the prices of these raw materials would not have a material impact on world markets or on the Corporation due to the widely available nature of these raw materials and the relatively small quantities that are used by the Corporation at any one time.

### **Regulatory Requirements**

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

#### *Canada*

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

#### *U.S.*

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

If a device is considered to be substantially equivalent to existing devices already marketed, it may receive a 510(k) clearance. Under this clearance, the FDA will send the manufacturer a market clearance letter called a substantially-equivalent letter. Although this process can be as short as 60 days, it is typical for a 510(k) approval to take 90 to 120 days. If a device does not qualify for a 510(k), a pre-market approval (“PMA”) process may be required. The length of the PMA process depends largely on the nature of the device and the diagnosis undertaken

through the use of the device and the resulting impact on clinical trial endpoints and design. Increasingly, the FDA is creating a more user-friendly regulatory environment, and, as a result, even the PMA process can proceed expeditiously.

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

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

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

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

## *Europe*



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

Before placing a medical device or IVD on the European Union (E.U.) market, the manufacturer must subject the product to the conformity assessment procedure that is provided in the applicable directive, with the intention of affixing a CE-mark to the product. Certain products, such as the Corporation's consumer version of the skin cholesterol test, currently in development, will require a third-party conformity assessment to be carried out by a "Notified Body", which is a public or private company designated by member states of the European Union to assess a product's conformity with the essential requirements of the medical device and IVD directives. Other products, such as Cholesterol 1,2,3, fall under the "Other" category of IVDs. Products in this category can be self-CE-marked by the manufacturer without the involvement of a "Notified Body". As well, all manufacturers outside of the E.U. are required to designate an "Authorized Representative" in the E.U. who can respond to queries from member states and customers with regard to a CE-marked product on behalf of the manufacturer.

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

The Corporation received HPB clearance for Cholesterol 1,2,3 in 2001, 510(K) clearance from the FDA for Cholesterol 1,2,3 in June 2002 and was CE-marked on September 5, 2002 for European marketing of Cholesterol 1,2,3. The other technologies of the Corporation are in various stages of clinical trials in the U.S. and Canada, and thus the timing for receipt of HPB and FDA clearance is uncertain. Generally, research and clinical data used to receive regulatory approval in one jurisdiction may be used for regulatory submissions in other jurisdictions.

The Corporation'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 the Corporation are in various stages of clinical trials in the U.S. and Canada, and thus the timing for receipt of HPB and FDA clearance is uncertain. Generally, research and clinical data used to receive regulatory approval in one jurisdiction may be used for regulatory submissions in other jurisdictions.

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

#### *Economic Dependence*

For the years ended December 31, 2004 and 2003, 100% of the Corporation's total revenue was generated from McNeil. See "Key Information - Risk Factors."

#### *Employees*

The Corporation currently has 18 full-time employees, 11 of whom are located at its head office in Toronto, Ontario and seven at its research laboratory in Hamilton, Ontario. In addition, the Corporation has contractual arrangements with a number of research scientists and organizations that provide staff and related services. These contracts provide flexible and directed research staff to the Corporation on an as-needed basis.

#### **C. Organizational Structure**

The Corporation carries on its operations in Canada. As at December 31, 2003 the Corporation had a wholly-owned subsidiary, IMI International Medical Innovations Inc. (Switzerland), a corporation incorporated under the laws of Switzerland. On March 23, 2004, the Corporation incorporated another wholly-owned subsidiary, 621178 Canada Inc., under the laws of Canada, to hold key man insurance coverage. 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

**D. Property, Plants and Equipment**

The Corporation currently rents approximately 3,500 square feet of office space at 4211 Yonge Street, Suite 615, Toronto, Ontario, M2P 2A9, Canada, its principal place of business. The Corporation also occupies laboratory facilities at McMaster University in Hamilton, Ontario, Canada under an agreement that expires on October 31, 2005 and is currently negotiating a new agreement with McMaster.

All assets are held in the name of the Corporation. The following table details the Corporation's fixed assets as of December 31, 2004:

	<b>Cost (\$)</b>	<b>Accumulated Depreciation (\$)</b>	<b>Net Book Value (\$)</b>
Manufacturing equipment	18,150	6,600	11,550
Computer equipment	270,704	143,925	126,779
Furniture and equipment	60,172	39,357	20,815
Research instrumentation	606,104	373,439	232,665
Laboratory equipment	25,501	7,735	17,766
Leasehold improvements	21,479	10,099	11,380
<b>TOTAL</b>	<b>1,002,110</b>	<b>581,155</b>	<b>420,955</b>

**ITEM 5. Operating and Financial Review and Prospects.**

*The following discussion and analysis should be read in conjunction with the audited financial statements and notes thereto for the years ended December 31, 2004, 2003 and 2002, which have been prepared in accordance with Canadian generally accepted accounting principles. Some of the statements contained in this Management's Discussion and Analysis of Financial Condition and Operating Results constitute forward-looking statements. These statements relate to future events or to the Corporation's future financial performance and involve known and unknown risks, uncertainties and other factors that may cause the Corporation's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by such forward-looking statements.*

**A. Operating Results***Year Ended December 31, 2004 Compared With the Year Ended December 31, 2003*

The consolidated loss for the year ended December 31, 2004 was \$5,569,000 (\$0.26 per share) compared with \$4,063,000 (\$0.19 per share) for the year ended December 31, 2003, an increase of \$1,506,000.

In 2004, the Corporation made initial shipments of PREVU\* Skin Sterol Test to its marketing partner, McNeil Consumer Healthcare, for total product-related sales of \$183,000. In Q2 2004, the Corporation completed a worldwide licensing agreement with McNeil to sell our cardiovascular products under the brand name PREVU\* Skin Sterol Test. The upfront cash payments from both the worldwide agreement and the original Canadian agreement of \$3,000,000 and \$100,000, respectively, have been deferred and are being recognized into income on a straight-line basis over the terms of the agreements (10 and 15 years, respectively). Thus, the amounts being recognized into income for 2004 and 2003 are \$182,000 and \$17,000, respectively. Furthermore, minimum sales levels in the agreement provided an additional \$120,000 revenue in 2004 which was reported as license revenue. Therefore, total license revenue amounted to \$302,000 for 2004 compared with \$17,000 in 2003.

Research and development expenditures for the year increased by \$694,000 to \$2,613,000 from \$1,919,000 in 2003. The variance for the year reflects the following:

• \$253,000 increase in spending on clinical trials for skin cholesterol and cancer to \$488,000 from \$235,000 in 2003. This increase is related to a lung cancer trial (the “I-ELCAP” study) and the large skin cholesterol study being conducted with AtheroGenics, Inc. that commenced in the latter part of 2003. The Corporation conducted at least 19 clinical trials during the year;

• increased filing fees on intellectual property, which amounted to \$196,000 compared with \$92,000 in fiscal 2003. During the year, the Corporation filed new patents on skin cholesterol in numerous European countries. In addition, the Corporation incurred costs of \$96,000 related to filing a petition for reinstatement of two U.S. patents for skin cholesterol that had been deemed abandoned. The Corporation is continuing to seek reinstatement;

• increases in total compensation and benefits for research personnel of \$221,000, reflecting annual increases plus accruals for incentive compensation based on performance;

• increases in subcontract research expenditures of \$114,000, as the Corporation continued further development of new prototypes of laboratory and consumer (over-the-counter) formats of the skin cholesterol technology; and

• a reduction in stock-based compensation, which was prospectively adopted in 2003, resulted in non-cash expenses for research personnel of \$124,000 in 2004 compared with \$189,000 for 2003, reflecting fewer options being granted in 2004.

General and administration expenses amounted to \$3,355,000 compared with \$2,362,000 in 2003, an increase of \$993,000. The increase for the year reflects:

- a one-time cost of \$478,000 in 2004 related to the Corporation's unsolicited offer to acquire the shares of IBEX Technologies Inc. ("IBEX"). The Corporation allowed the offer to expire in December 2004 and did not complete the purchase;
- a \$221,000 increase in stock-based compensation for options for administrative personnel that resulted in a non-cash expense of \$476,000 for the year compared with \$255,000 for 2003. This increase was primarily for options granted in 2004 pursuant to a U.S. consulting contract that vested over nine months and for the cashless exercise of options by an officer of the Corporation;
- an \$80,000 increase in professional fees, primarily due to legal fees related to finalizing the global licensing agreement with McNeil;
- a \$64,000 increase in insurance premiums over 2003 as a result of listing on the American Stock Exchange ("Amex");
- a reduction to nil in 2004 (\$179,000 in 2003) for costs related to the Corporation's U.S. listing on Amex, which was completed in September 2003;
- a reduction in travel expenses by \$76,000 following completion of the McNeil agreement as a result of less foreign travel; and
- an increase of \$160,000 in total compensation and benefits for administration personnel reflecting annual increases plus accrued incentive compensation based on performance.

On November 2, 2004, the Corporation announced an unsolicited offer to acquire all of the issued and outstanding common shares of IBEX, a Toronto Stock Exchange ("TSX")-listed company based in Montreal that is focused on the development of technologies for the management of cancer and arthritis. The offer expired on December 16, 2004 without the Corporation taking up any shares of IBEX.

Amortization expenses for equipment and acquired technology for 2004 amounted to \$224,000 compared to \$281,000 in 2003. Purchases of equipment amounted to \$165,000 in 2004 and \$386,000 in 2003.

Recoveries of provincial scientific investment tax credits ("ITCs") amounted to \$205,000 for 2004 compared with \$223,000 in 2003. The December 2003 tax credit receivable of \$180,000 has not yet been received from the government and is still outstanding.

Interest income amounted to \$124,000 for 2004, compared with \$258,000 for 2003, reflecting lower interest rates on invested cash and lower cash balances through most of the year.

*U.S. GAAP*

For purposes of U.S. GAAP, the consolidated loss for 2004 was \$5,478,000 compared with \$3,949,000 in 2003.

*Other*

There is a significant increase of \$882,000 in accounts payable in 2004 compared with 2003. This includes the purchase of inventory of approximately \$340,000 in December, clinical trial costs of \$85,000 and most of the expenses related to the IBEX offer.

*Year Ended December 31, 2003 Compared With the Year Ended December 31, 2002*

The consolidated loss for the year ended December 31, 2003 was \$4,063,000 (\$0.19 per share) compared with \$4,018,000 (\$0.20 per share) for the year ended December 31, 2002, an increase of \$45,000.

Research and development expenditures for fiscal 2003 decreased to \$1,919,000, compared with \$2,105,000 for fiscal 2002. Clinical trial expenses, which consist principally of fees paid to third parties, decreased by approximately \$330,000 from 2002. This resulted from changes both in the mix and timing of the trials. The Corporation conducted at least 15 clinical trials during the year, but several of them are subsidized through collaborative arrangements with third parties, thereby significantly reducing the Corporation's expenses. In addition, several large trials were committed to near the end of the fiscal year, so most of those expenses would be incurred in 2004 and beyond. The cost of registering and maintaining intellectual property decreased to \$92,000 compared to \$251,000 in 2002 when extra costs to register new technologies were incurred. In 2002, the Corporation adopted the accounting for stock-based compensation for non-employees and stock granted to employees, using the fair value method. In 2003, the Corporation prospectively adopted the new recommendations to expense stock-based compensation to employees, rather than waiting until 2004. The stock-based compensation costs that related to research and development amounted to a non-cash expense of \$189,000 compared with \$82,000 for 2002.

General and administration expenses amounted to \$2,362,000 for 2003, compared with \$2,141,000 for 2002, an increase of \$221,000. Expenses related to registering with the U.S. SEC and listing on Amex amounted to approximately \$179,000 for 2003 compared with \$260,000 in 2002. The Corporation's shares commenced trading on Amex in September 2003. Compensation expense increased by \$99,000 in 2003, an increase of 14%, reflecting the addition of one employee plus annual increases. Cash compensation for directors' fees, which commenced in the fourth quarter of 2002, amounted to \$61,500 for 2003 compared with \$14,750 for 2002. Stock-based compensation relating to administration resulted in non-cash expenses of \$255,000 compared with \$36,000 in 2002.

Amortization expenses for 2003 amounted to \$281,000 compared with \$219,000 for 2002. Of the fiscal 2003 expense, \$167,000 was amortization on capital equipment and \$114,000 was amortization on acquired technologies (\$77,000 and \$142,000, respectively, in 2002). Additions of capital equipment during 2003 and 2002 amounted to \$386,000 and \$21,000, respectively, and were primarily in support of clinical trials.

Recoveries of provincial ITCs amounted to \$223,000 for the year. This includes an accrual of \$180,000 for 2003. In 2002 management recorded its best estimate of the recovery for the year. In 2003, the actual recovery for 2002 exceeded management's estimate by \$43,000.

Interest income for 2003 was \$258,000 compared with \$257,000 for 2002, an increase of \$1,000, due to higher average cash balances.

*U.S. GAAP*

For purposes of U.S. GAAP, the consolidated loss for 2003 was \$3,949,000, compared with \$4,871,000 for 2002. The adjustment for stock and stock option compensation expense for U.S. GAAP, in addition to the Canadian GAAP expense recognized, amounted to nil in 2003 compared with \$995,000 in 2002 when 206,000 performance-based options vested.





**B. Liquidity and Capital Resources**

As at December 31, 2004, the Corporation had cash, cash equivalents and short-term investments totaling \$5,196,000 (\$6,697,000 as at December 31, 2003). The Corporation invests its funds in Canadian dollars in short-term financial instruments and marketable securities. In Q2 2004, the Corporation received a \$3,000,000 upfront payment upon the signing of the worldwide marketing agreement with McNeil. Thus, net cash used in operating activities during the year amounted to \$1,370,000 compared with \$3,396,000 in 2003. The Corporation has no long-term debt.

**C. Contractual Commitments**

The Corporation has certain contractual obligations and commitments related to ongoing clinical trials and research agreements as follows:

	Total	Less than 1 Year	1 - 2 Years	2-5 Years
Clinical Trials	\$ 908,000	\$ 618,000	\$ 290,000	–
Research Agreements	\$ 90,000	\$ 90,000	nil	–
Other	\$ 115,000	\$ 115,000	nil	–
Total	\$ 1,113,000	\$ 823,000	\$ 290,000	–

Certain other obligations, totaling up to \$360,000, are only payable upon the achievement of specific events.

To date, the Corporation has financed our activities through the issuance of shares and the recovery of provincial ITCs. Management believes that, based on historic cash expenditures and the current expectation of further revenues from product sales and royalties, the Corporation's existing cash resources together with the investment tax credits receivable of \$389,000 will be sufficient to meet our current operating and capital requirements through at least 2005. However, the Corporation's future capital requirements will depend on many factors, including sales and license revenue growth, 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.

The Corporation is exposed to financial market risks such as interest rates and foreign exchange fluctuations. The Corporation's cash is invested in short-term, high-grade securities with varying maturities. Since the Corporation's intention is to hold these securities to maturity, adverse changes in interest rates would not have a material effect on the Corporation's results of operations. The Corporation 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 the Corporation.

**D. Research and Development**

In fiscal 2004, the Corporation's research and development expenditures for the year increased by \$694,000 to \$2,613,000 from \$1,919,000 in 2003.

Below is a summary of the Corporation's products and the related stages of development in 2004 for each product in clinical development. The information in the columns labeled "Approximate Percentage Completed" and "Estimate of Completion of Phase" contain 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 provided in the table. For a discussion of the risks and uncertainties associated with the timing of completing a product development phase, see "Key Information - Risk Factors" and "Information on the Corporation - Business Overview."



<b>Product</b>	<b>Description / Indication</b>	<b>Phase of Development</b>	<b>Approx. % Completed</b>	<b>Collaborator</b>	<b>Estimate of Completion of Phase</b>
Coronary Artery Disease (CAD) Risk Assessment Technology:					
PREVU* POC Skin Sterol Test (previously Cholesterol 1,2,3™)	Point of care skin cholesterol test that provides information about an individual's risk of coronary artery disease; clinical studies to expand indication for use	Regulatory clearance in Canada, U.S. and Europe; start of sales by McNeil	100%	McNeil	2005
		Expand regulatory claims	5%	Various clinical trial sites	2006
PREVU* LT Skin Sterol Test	Lab-processed skin cholesterol test	Clinical trials in progress	10%	McNeil	2005/06
		Commercial launch in select markets	0	McNeil	2005/06
PREVU* PT Skin Sterol Test	Consumer version of the skin cholesterol test	Product development	50%	McNeil	2005
Cancer Technologies:					
ColorectAlert™ & Colopath™	Mucus tests for early detection of colorectal cancer	2,000 patients tested in clinical trials	100%	St. Michael's Hospital	2004
		Clinical studies to support commercialization	10%	N/A	2006
LungAlert™	Sputum test for early detection of lung cancer	1,000 patients tested in clinical trials	60%	St. Joseph's Hospital;	2005/06

		trials		I-ELCAP	
		Expand clinical trials; publish scientific papers	0		2006
Breast Cancer Test	Aspirate test for early detection of breast cancer	Pivotal study underway	10%	University of Louisville	2005/06
All Cancer Tests	Improvement of assay method	Alternative format development	50%	N/A	2005

In connection with the Corporation's research agreements and research and development arrangements, the Corporation is committed to make minimum annual payments of \$120,000 until October 31, 2005. Also see "Information on the Corporation - Business Overview."

The table below sets out the estimated costs incurred for each of the Corporation's products for the years ended December 31, 2004, 2003, 2002, and the 11-month period ended December 31, 2001. In addition, a historical cumulative total of costs incurred since February 1997, per product, has been provided. Prior to February 1997, the Corporation did not track its costs by project.

Product	Fiscal Year	Fiscal Year	11-Month	Fiscal Year	Historical
	Ended	Ended	Period Ended	Ended	Cumulative
	Dec. 31, 2004	Dec. 31, 2003	Dec. 31, 2002	Dec 31, 2001	total since
					Feb. 1, 1997
CAD Risk Assessment Technologies	\$ 1,476,000	\$ 860,000	\$ 1,188,000	\$ 1,297,000	\$ 6,542,000
ColorectAlert™ and ColoPath™	\$ 304,000	\$ 327,000	\$ 495,000	\$ 488,000	\$ 2,681,000
LungAlert™	\$ 255,000	\$ 228,000	\$ 178,000	\$ 118,000	\$ 829,000
Breast Cancer	\$ 42,000	\$ 45,000			\$ 87,000

The Corporation expects to generate revenues from sales of PREVU\* in the calendar year 2005. The Corporation anticipates that costs to complete the development of new formats and clinical trials of the coronary artery disease technologies will not exceed \$3 million.

With respect to the Corporation's cancer-related products, the Corporation estimates that the costs to complete clinical trials and commercialize the colorectal cancer technology will not exceed \$3.5 million. However, given the nature and uncertainty of ultimately receiving regulatory clearance for these cancer-related products, the Corporation is unable to reasonably estimate the timing of these projects' commercialization.

#### ***E. Trend Information***

See "Information on the Corporation - Business Overview."

#### ***F. Off-Balance Sheet Arrangements***

The Corporation has no material Off Balance Sheet arrangements.

### **ITEM 6. Directors, Senior Management and Employees.**

#### ***A. Directors and Senior Management.***

##### **SENIOR MANAGEMENT**

*Brent Norton, MD, MBA, 44, President and CEO, Director*

Dr. Norton founded the Corporation in 1992 and has since served as President and Chief Executive Officer and as a director of the Corporation. Active in medical practice, management and research for over 15 years, Dr. Norton has represented and led multiple medical groups and scientific initiatives. As a physician-entrepreneur, his cross-functional knowledge and skills enable him to guide the Corporation and its products from the scientific stage through to successful commercialization.

Dr. Norton serves as a director on the boards of public and private medical companies in Canada and the U.S. and is an Advisory Council Member of the Richard Ivey School of Business MBA Biotech Program. He is also an active volunteer, previously serving as Chairman, Friends Project, for the Canadian Institute for Advanced Research, and as a committee member of a Canadian Intergovernmental Economic Commission, Advanced Technology Group.

Dr. Norton completed his medical training at McGill University in Montreal, Quebec in 1984. He subsequently completed a Master of Business Administration degree at the Richard Ivey School of Business, University of Western Ontario, in London, Ontario, Canada, in 1989.

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*Tim Currie, BA, 41, Vice President, Corporate Development*

Mr. Currie joined the Corporation on January 4, 2000 as Director, Business Development. On June 16, 2004, Mr. Currie was promoted to his current position. His career includes 15 years of experience in the pharmaceutical and health information fields in various senior sales and marketing positions for large multinational companies.

He is responsible for developing and implementing corporate business plans and for building alliances with other companies and organizations that complement the Corporation and drive its products towards commercialization. He leads efforts to acquire new technologies that fit with the Corporation's vision, and manages the Company's licensing initiatives for the marketing and distribution of products.

Mr. Currie has a degree in economics from the University of Western Ontario, and is active in a number of community organizations.

*Michael Evelegh, Ph.D., 52, Executive Vice President, Clinical and Regulatory Affairs*

Dr. Evelegh joined the Corporation on April 1, 1997 in the position he currently holds as the Corporation's Executive Vice President, Clinical and Regulatory Affairs.

Dr. Evelegh has nearly 20 years of experience researching and developing human diagnostics, including product development, clinical trials, regulatory submissions and manufacturing. Dr. Evelegh leads the Corporation's scientific team at the Corporation's laboratory located at McMaster University in Hamilton, Ontario. He is also chiefly responsible for evaluating the scientific potential of new technologies for the Corporation's pipeline of products.

Prior to joining the Corporation Dr. Evelegh was the Director of Research and Development for Biomira Diagnostics Inc., a medical technology company. He also directed research teams at other Canadian biotechnology companies and has been an independent scientific and regulatory consultant. He earned his Ph.D. in Immunology at McMaster University, where he is an Associate Professor in the university's medical school.

*Ron Hosking, 60, Vice President, Finance and Chief Financial Officer*

Mr. Hosking joined the Corporation on September 25, 1997 in the position he currently holds as the Corporation's Vice President, Finance and Chief Financial Officer.

Mr. Hosking's career includes 20 years in the health care industry managing the finances of multinational and early-stage companies. Prior to joining the Corporation, Mr. Hosking was Vice President and Chief Financial Officer of LifeTECH Corporation, a biotechnology corporation, from 1996 to 1997. Prior to that time, Mr. Hosking had been Vice President and Chief Financial Officer of Biomira Diagnostics, Inc and of Ortho Diagnostics Inc. (a Johnson & Johnson company). He is a Chartered Accountant and completed his B.Comm at the University of Toronto in Toronto, Ontario, Canada.

Mr. Hosking has been actively involved in industry and professional associations, including tenures as Chairman of the Board of Medical Devices Canada (MEDEC) and President of Financial Executives International (FEI) Toronto. He is currently a member of FEI, the Canadian Investor Relations Institute (CIRI), the Toronto Biotechnology Initiative (TBI) and the Toronto Board of Trade.

**DIRECTORS**



*Stephen A. Wilgar, BA, MBA, 67, Chairman of the Board*

Mr. Wilgar has served as one of the Corporation's directors since March 17, 1993. From May 2001 to June 2002, Mr. Wilgar was also a Director of Dimethaid Research Inc. and from June 1991 to April 2002, he was a Director of Verity International. In addition, he has served as Chairman of AIM Powergen Corp. and Team IMS from January 2002 to the present and as Director of Electrohome Ltd. from January 2004 to the present. Prior to that, Mr.

Wilgar was a Director of MedExtra Corp. from December 2001 to March 2002 and was the President of SunBlush Technologies Corporation from 1996 to 1999. From 1974 to 1988 he also served as President of Warner-Lambert Canada, Asia, Australia and Latin America. He is also a former President of the Canadian Automobile Association, Central Ontario.

*H.B. Brent Norton, MD, MBA, 44, Director*

See description above under “Directors, Senior Management and Employees - Directors and Senior Management - Senior Management.”

*John Carroll, BA, MBA, 71, Director*

Mr. Carroll served as a director of the Corporation from June 6, 1994 to 2005. Mr. Carroll is a Director of Clairon Holdings (from 1997) and SCOR Reinsurance of Canada. Prior to that, he was a Director of AXA Assurance Insurance Co. Ltd. from 1997 to 2004, Battery Technologies Inc. from 1996 to 2002, Quaker Oats of Canada from 1979 to 1992, Scott Paper Limited from 1994 to 1996 and Executive Chairman of Molson Breweries of Canada during the years of 1992 and 1993. Mr. Carroll retired from IMI’s Board of Directors on May 25, 2005.

*Anthony F. Griffiths, BA, MBA, 74, Director*

Mr. Griffiths has served as one of the Corporation’s directors since July 13, 1995. From 1997 and 2004, respectively, to the present, Mr. Griffiths has served as Director and Chairman of Russel Metals Inc. and Leitch Technology Corporation (Director since 1994). In addition, Mr. Griffiths is a Director of numerous companies, including Fairfax Financial Holdings Limited from 2002, Vitran Corporation Inc from 1987, Alliance Atlantis Communications Inc. from 1996, Hub International Limited from 1998, Northbridge Financial Corporation from 2003, Odyssey Re Holdings Corp. from 2001 and Jaguar Mining from 2004 to the present. From 1987 to 1993, Mr. Griffiths was Chairman of Mitel Corporation, also serving as President and Chief Executive Officer from 1991 to 1993. From 1994 and 2000, respectively, to 2004, Mr. Griffiths served as Director and Chairman of Slater Steel Inc. and Brazilian Resources Inc. He was also a Director of ShawCor from 1980 to 2004, Teklogix International Inc. from December 1998 to September 2000, Calian Technology Ltd. from 1993 to 2004, Canadian Tire Corporation from 1988 to 1998, QLT Inc. from 1988 to 2002 and Consumers Packaging Inc. from 2000 to 2002.

*Ronald D. Henriksen, MBA, 66, Director*

Mr. Henriksen has served as one of the Corporation’s directors since June 16, 2005. Mr. Henriksen has 34 years of experience in healthcare, working in the pharmaceutical, biotechnology, consulting, technology transfer and venture capital industries. Since March 2002, Mr. Henriksen has served as the Chief Investment Officer of Twilight Ventures, LLC, an Indianapolis-based venture capital firm investing exclusively in life science companies. Since January 1, 2005 and February 1, 2005, respectively, he has served as Chief Executive Officer of Semafore Pharmaceuticals, Inc., and as President and Chief Executive Officer of EndGenitor Technologies Inc.

Previously, Mr. Henriksen was the President of ARTI (Indiana University’s Advanced Research & Technology Insititute) from November 1998 until March 2002.

Mr. Henriksen has served on the board of directors of CyberLearning Labs, QLT, Inc., TGN Biotech, Macro Pore BioSurgery and BioStorage Technologies since 2000, 1997, 2002 2001 and 2003, respectively. He received his Bachelor of Science in Industrial Administration at Iowa State University and a Masters of Business Administration “with distinction” from the Harvard Business School.

*David Rosenkrantz, P. Eng., 47, Director*

Mr. Rosenkrantz has served as one of the Corporation's directors since June 11, 1998. Mr. Rosenkrantz has been President and Director of Patica Securities Limited since 1993 and is the founding partner of Patica Corporation, a merchant banking corporation. In addition, Mr. Rosenkrantz has served as Director of Stellar Pharmaceuticals Inc. since 2002 (Chairman from 2002 to 2004), Versent Corporation since 1993 (Chairman since 2004), Neuromolecular Inc. since 2001, Carfinco Income Fund since 2002, Medisystem Technologies Inc. since 2004 and RAS Completions

Inc. since 2000. He was also a Director of LymphoSign Inc. from 2000 to 2003, Northern Mountain Helicopter Group Inc. from 1996 to 2000 and Beta Brands Inc. from 1993 to 1995.

## SCIENTIFIC ADVISORY BOARD

The role of the Scientific Advisory Board (the “SAB”) is to provide the Corporation with 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 members of the Scientific Advisory Board include:

*Dr. John Bienenstock, FRCP, FRCPC, FRSC*

Dr. Bienenstock was appointed to the SAB in May 1998. He is a Professor, Departments of Medicine and Pathology, Faculty of Health Sciences, McMaster University, Hamilton, Ontario, Canada. Dr. Bienenstock is an internationally renowned physician and scientist and was awarded the Order of Canada in 2002 in recognition of his contribution to medicine.

*Dr. Herbert A. Fritsche, Jr., Ph.D.*

Dr. Fritsche was appointed to the SAB in January 2000. He is the Chief of Clinical Chemistry and Professor of Biochemistry, Department of Pathology and Laboratory Medicine, University of Texas M.D. Anderson Cancer Center, Houston, Texas. He has been with M.D. Anderson Cancer Center for over 30 years and has been the recipient of many awards, including the Distinguished Scientist Award for 1999 by the Clinical Ligand Assay Society.

*Dr. Norman Marcon, M.D., FRCP*

Dr. Marcon was appointed to the SAB in April 2000. He is a Gastroenterologist and Past-Chief, Division of Gastroenterology of St. Michael’s Hospital, Toronto, Ontario, Canada. He has been with St. Michael’s Hospital since 1972. Dr. Marcon is a Fellow, Royal College of Physicians and Surgeons of Canada and is a recipient of The Ontario Association of Gastroenterology Lifetime Achievement Award. He is also Associate Professor of Medicine, University of Toronto, Toronto, Ontario, Canada.

*Dr. Dennis L. Sprecher, MD*

Dr. Sprecher was appointed to the SAB in April 1999. He is Director, Dyslipidemia Discovery Medicine at GlaxoSmithKline, Pennsylvania, USA. He was formerly the Section Head, Preventive Cardiology & Rehabilitation, The Cleveland Clinic Foundation, where he continues to serve as Cardiologist, Adjunct Staff. He is also an Adjunct Professor, University of Pennsylvania Department of Cardiology, University of Pennsylvania Medical Center Presbyterian. Prior to joining the Cleveland Clinic in 1995, Dr. Sprecher was the Section Head of Preventative Cardiology at the University of Cincinnati, Cincinnati, Ohio.

## **B. Compensation**

### **1. Summary Compensation Table**

The following table is a summary of the compensation paid by the Corporation to its: (i) President and Chief Executive Officer; (ii) Executive Vice President, Clinical and Regulatory Affairs; (iii) Vice President, Finance and Chief Financial Officer; and (iv) Vice President, Corporate Development (collectively, the “Named Executive Officers”) for the years ended December 31, 2004, 2003 and 2002.



Name and Position	Financial Year Ended	Annual Compensation			Long-term Compensation	
		Salary (\$)	Bonus (\$)	Other Annual Compensation <sup>(1)</sup> (\$)	Securities Under Option Granted (#)	All other Compensation (\$)
Dr. Brent Norton President and Chief Executive Officer	Dec. 31, 2004	\$285,000	\$142,500	-	-	-
	Dec. 31, 2003	\$285,000	-	-	70,000	-
	Dec. 31, 2002	\$222,500	\$45,000	-	360,000	\$6,750 <sup>(2)</sup>
Ronald Hosking Vice President, Finance and Chief Financial Officer	Dec. 31, 2004	\$167,500	\$30,000	-	-	-
	Dec. 31, 2003	\$150,000	\$24,000	-	85,000	-
	Dec. 31, 2002	\$126,000	-	-	36,000	\$6,750 <sup>(2)</sup>
Michael Evelegh Ph.D., Executive Vice President, Clinical and Regulatory Affairs	Dec. 31, 2004	\$225,000	\$56,250	-	-	-
	Dec. 31, 2003	\$225,000	-	-	50,000	-
	Dec. 31, 2002	\$215,000	\$105,000	-	110,000	-
Tim Currie Vice President, Corporate Development	Dec. 31, 2004	\$150,000	\$45,000	-	35,000	-

**Notes:**

(1) Unless otherwise disclosed, the aggregate amount of perquisites and other personal benefits do not exceed the lesser of \$50,000 and 10% of the salary and the bonus of each Named Executive Officer for the years ended December 31, 2004, 2003 and 2002.

(2) This compensation reflects the value of the Common Shares issued by the Corporation to such Named Executive Officers pursuant to the Corporation's employee share purchase plan. The value is based upon the closing price of the Common Shares on the Toronto Stock Exchange on the respective dates of the issuance of such shares. See "Executive Compensation - Employee Share Purchase Plan".

## 2. Long-term Incentive Plan Awards during the Year Ended December 31, 2004

No Long-term Incentive Plan Awards were made to the Named Executive Officers during the year ended December 31, 2004.



### 3. Option Grants during the Year Ended December 31, 2004

During the year ended December 31, 2004, the following incentive stock options were granted to the Named Executive Officers:

Name and Position	Securities Under Options Granted (#) <sup>(1)</sup>	% of Total Options Granted to Employees in Financial Year	Exercise or Base Price (\$/Security)	Market Value of Securities Underlying Options on the Date of Grant (\$/Security)	Expiration Date
Tim Currie Vice President, Corporate Development	35,000	13.5%	\$4.00	\$4.00	Feb. 23, 2009

**Note:**

(1) These options will vest annually over a period of five years.

### 4. Aggregated Option Exercises during the Year Ended December 31, 2004 and Financial Year-end Option Values

The following table sets out (i) the number of Common Shares issued to the Named Executive Officers upon the exercise of options during the year ended December 31, 2004 and the aggregate value realized upon such exercises; and (ii) the number and value of unexercised options held by the Named Executive Officers as at December 31, 2004:

Name and Position	Securities Acquired on Exercise (#)	Aggregate Value Realized (\$)	Unexercised Options at FY-End (#) Exercisable/Unexercisable	Value of Unexercised in-the-money Options at FY-End (\$) Exercisable/Unexercisable <sup>(4)</sup>
Dr. Brent Norton, President and Chief Executive Officer	27,713 <sup>(1)</sup>	\$94,500 <sup>(1)</sup>	550,000 <sup>(2)</sup> / 447,500 <sup>(3)</sup> /102,500	\$33,600 / \$28,350/\$5,250
Ronald Hosking, Vice President, Finance and Chief Financial Officer	-	-	121,000 <sup>(2)</sup> / 42,200 <sup>(3)</sup> /78,800	\$7,500 / \$1,500/\$6,000
Michael Evelegh, Ph.D., Executive Vice	-	-	220,000 <sup>(2)</sup> / 167,500 <sup>(3)</sup> /52,500	\$7,000 / \$5,250/\$1,750



President, Clinical and  
Regulatory Affairs

Tim Currie	-	-	221,000 <sup>(2)</sup> /	\$42,500 /
Vice President, Corporate Development			95,400 <sup>(3)</sup> /125,600	\$26,000/\$16,500

**Notes:**

- (1) On September 13, 2004, Dr. Norton exercised, on a cashless basis, options to acquire 75,000 Common Shares at an exercise price of \$2.15 per share. Upon such exercise, the Corporation issued 27,713 Common Shares to Dr. Norton with an aggregate value equal to the difference between the exercise price of the options and the fair market value of the Common Shares as at such date. The Toronto Stock Exchange and the Board of Directors of the Corporation approved this cashless exercise.
- (2) These options will vest (i) upon the occurrence of certain performance-related milestones of the Corporation relating to the Corporation's core technologies (e.g. launch of clinical trials, FDA clearance of initial claims); (ii) based upon the Corporation's financial performance (e.g. earnings per share targets); and/or (iii) annually over a pre-determined number of years.
- (3) These options were not yet exercisable as the milestones or time periods referred to in note (1) above had not yet been attained.
- (4) Based upon a closing price of \$3.00 for the Common Shares on the Toronto Stock Exchange on December 31, 2004.

*Employee Share Purchase Plan*

The Corporation implemented a share purchase plan (the "Purchase Plan") in March 1999 whereby the Corporation will match the value of the Common Shares purchased by its employees, officers and directors in the market by issuing from treasury an equal number of Common Shares, up to a maximum value of the lesser of (i) 50% of the maximum allowable annual contribution for registered retirement savings plans as established by the Canada Revenue Agency; and (ii) 9% of the participant's annual salary.

The maximum number of Common Shares which may be issued by the Corporation pursuant to the Purchase Plan is 350,000. As at April 15, 2005, the Corporation has issued an aggregate of 100,019 Common Shares under the Purchase Plan to its employees, officers and directors.

**C. Board Practices**

The Corporation's Board of Directors and senior management consider good corporate governance to be central to the effective and efficient operations of the Corporation. The following table lists the directors of the Corporation, the positions they hold with the Corporation and the dates the directors were first elected or appointed:

<b>Name</b>	<b>Position</b>	<b>Term</b>
Dr. H.B. Brent Norton	President, Chief Executive Officer and Director	President, CEO: 1992-present Director: March 17, 1993-present
Stephen A. Wilgar	Director and Chairman	March 17, 1993-present
John C. Carroll	Director	June 6, 1994-May 25, 2005
Anthony F. Griffiths	Director	July 13, 1995-present
Ronald D. Henriksen	Director	June 16, 2004-present
David A. Rosenkrantz	Director	June 11, 1998-present

The Board of Directors was elected at the annual meeting of shareholders on June 16, 2004, and each director will serve until the next annual meeting of shareholders or until their resignation. During the year ended December 31, 2004, a total of \$72,000 was paid to the directors of the Corporation in their capacity as directors. The directors of the Corporation are eligible to receive options to purchase Common Shares pursuant to the terms of the Corporation's incentive stock option plan. During the financial year ended December 31, 2004, options to purchase an aggregate of 90,000 Common Shares were granted to the non-executive directors. (see "Directors, Senior Management and Employees - Share Ownership - Stock Option Plan"). None of the directors or executive officers of the Corporation have directors' service contracts with the Corporation or its subsidiary providing for benefits upon termination of employment.

At the 2005 annual meeting of shareholders, held May 25, 2005, Messrs. Wilgar, Griffiths, Henriksen, Norton and Rosenkrantz were re-elected to the Board of Directors. John C. Carroll retired from the Board of Directors on that date.

The Corporation has entered into employment agreements with each of Dr. Norton and Dr. Evelegh. Each of these employment agreements sets out the obligations of such Named Executive Officers to the Corporation and the compensation to be paid to them. These Named Executive Officers' compensation includes a combination of base salary, cash bonus, stock options and other benefits.

Unless terminated earlier pursuant to the terms of their respective agreements, the employment with the Corporation of Dr. Norton and Dr. Evelegh shall continue indefinitely. If the employment of such Named Executive Officers is terminated by the Corporation without cause or, at their option, terminated in the event of a "change of control" (as such term is defined in their respective employment agreements) of the Corporation, he is entitled to cash payments equal to a percentage of his then current annual base salary. Also, in the event of termination without cause or termination by Dr. Norton or Dr. Evelegh in the event of a change of control, all of his options shall immediately vest and shall be exercisable or convertible for a period of 60 days after such termination. Each of Dr. Norton and Dr. Evelegh has agreed not to compete with the Corporation (for two years for Dr. Norton and for one year for Dr. Evelegh) in the event that he is terminated with or without cause or if he voluntarily resigns from the Corporation.

Unless terminated earlier pursuant to his employment agreement, Mr. Hosking's employment shall continue until January 2006 at which time it may be renewed for successive one-year periods. If Mr. Hosking's employment is terminated without cause, he is entitled to a cash payment equal to a percentage of his then current annual base salary and all options held by Mr. Hosking shall immediately vest and shall be exercisable or convertible for a period of 30 days after such termination. Mr. Hosking has also agreed not to compete with the Corporation for one year in the event that he is terminated for cause.

For 2004, the compensation committee of the Corporation's Board of Directors was made up of John C. Carroll, Anthony F. Griffiths, David A. Rosenkrantz and Stephen A. Wilgar, all of which are outside directors. For 2005, the compensation committee is composed of Anthony F. Griffiths, David A. Rosenkrantz and Stephen A. Wilgar. The compensation committee meets on compensation matters as and when required with respect to executive compensation. The primary goal of the compensation committee is to ensure that the compensation provided to the Named Executive Officers and the Corporation's other senior officers is determined with regard to the Corporation's business strategies and objectives, such that the financial interest of the senior officers is matched with the financial interest of shareholders. They also ensure that the Named Executive Officers and the Corporation's senior officers are paid fairly and commensurably with their contributions to furthering the Corporation's strategic direction and objectives. The Corporation also grants stock options to its officers, directors and employees from time to time in accordance with the Corporation's stock option plan.

For 2004, the audit committee of the Corporation, composed entirely of outside directors, was made up of Stephen A. Wilgar, John C. Carroll, Anthony F. Griffiths and David A. Rosenkrantz, each of which meets the independence requirements of the listing standards of the American Stock Exchange. For 2005, the audit committee is composed of Stephen A. Wilgar, Anthony F. Griffiths and David A. Rosenkrantz. Mr. Rosenkrantz is the Chair of the audit committee. The audit committee has primary responsibility for ensuring the integrity of the Corporation's financial reporting, risk management and internal controls. The audit committee has unrestricted access to the Corporation's personnel and documents and has direct communication channels with the Corporation'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 the Corporation 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.



**D. Employees**

The Corporation currently employs 18 full-time employees, nine of whom are located at its head office in Toronto, Ontario, Canada, and eight at its research laboratory in Hamilton, Ontario, Canada. In addition, the Corporation has contractual arrangements with a number of research scientists and organizations that provide staff and related services. These contracts provide flexible and directed research staff to the Corporation on an as-needed basis.

**E. Share Ownership**

The following table shows the number of Common Shares and options to purchase Common Shares beneficially owned by each director and the Named Executive Officers as of April 30, 2005.

<b>Name</b>	<b>Common Shares held directly and beneficially</b>	<b>% of Outstanding Common Shares as of April 30, 2003</b>	<b>Options outstanding</b>	<b>Exercise price</b>	<b>Expiration date</b>
Dr. H.B. Brent Norton	2,421,748	11.2%	120,000	\$	3.45 Feb. 1, 2006
			120,000	\$	4.00 Feb. 16, 2007
			240,000	\$	2.86 Nov. 16, 2007
			70,000	\$	4.00 Dec. 5, 2008
			100,000	\$	2.95 Feb. 6, 2010
Michael Eveleigh, Ph.D	379,261	1.8%	60,000	\$	3.50 Feb. 1, 2006
			60,000	\$	4.00 Feb. 16, 2007
			50,000	\$	2.86 Nov. 16, 2007
			50,000	\$	4.00 Dec. 5, 2008
Ronald G. Hosking	283,778	1.3%	36,000	\$	4.00 Feb. 16, 2007
			50,000	\$	2.85 Jun 27, 2008
			35,000	\$	4.00 Dec. 5, 2008
			65,000	\$	2.95 Feb. 6, 2010
			52,000	\$	2.95 Feb. 6, 2010
Tim Currie	4,000	0.0%	70,000	\$	2.50 Feb. 1, 2006
			20,000	\$	3.45 Mar. 1, 2006
			10,000	\$	3.60 Mar. 20, 2006
			36,000	\$	4.00 Feb. 16, 2007
			50,000	\$	2.85 Mar. 3, 2008
			35,000	\$	4.00 Feb. 23, 2009
			52,000	\$	2.95 Feb. 6, 2010
Stephen A. Wilgar	275,038	1.3%	20,000	\$	4.61 July 17, 2005
			10,000	\$	2.86 Nov. 16, 2007
			30,000	\$	4.00 Dec. 5, 2008
			30,000	\$	4.09 Aug. 7, 2009

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John C. Carroll	263,442	1.2%	10,000	\$	4.61	July 17, 2005
			5,000	\$	2.86	Nov. 16, 2007
			15,000	\$	4.00	Dec. 5, 2008
			15,000	\$	4.09	Aug. 7, 2009

Name	Common Shares held directly and beneficially	% of Outstanding Common Shares as of April 30, 2003	Options outstanding	Exercise	
				price	Expiration date
Anthony F. Griffiths	510,500	2.4%	10,000	\$ 4.61	July 17, 2005
			5,000	\$ 2.86	Nov. 16, 2007
			15,000	\$ 4.00	Dec. 5, 2008
			15,000	\$ 4.09	Aug. 7, 2009
David A. Rosenkrantz	346,133	1.6%	10,000	\$ 4.61	July 17, 2005
			5,000	\$ 2.86	Nov. 16, 2007
			15,000	\$ 4.00	Dec. 5, 2008
			15,000	\$ 4.09	Aug. 7, 2009
Ronald Henriksen	0	0.0%	15,000	\$ 3.50	Apr. 12, 2009

*Employee Share Purchase Plan*

See description above under “Directors, Senior Management and Employees - Compensation - Employee Share Purchase Plan.”

*Stock Option Plan*

The Corporation established an incentive stock option plan (the “Plan”) on June 11, 1998, as amended, in order to encourage directors, senior officers, employees and consultants of the Corporation to acquire a proprietary interest in the Corporation and to provide an incentive to such persons related to the performance of the Corporation.

Under the Plan, which is administered by the Board of Directors of the Corporation, options to acquire Common Shares may be granted to persons, firms or companies who are employees, senior officers, directors or consultants of the Corporation or any subsidiary of the Corporation. Currently, the number of Common Shares reserved for issuance from time to time under the Plan shall not exceed 3,500,000 Common Shares.

The directors of the Corporation may from time to time grant options to eligible optionees. At the time an option is granted, the directors shall determine the number of Common Shares issuable under the option, the date when the option is to become effective and, subject to the other provisions of the Plan and subject to applicable laws and regulations, all other terms and conditions of the option. No one optionee may, at any time, receive options entitling the optionee to purchase more than 5% of the outstanding Common Shares, calculated on an undiluted basis, less the aggregate number of Common Shares reserved for issuance to such person under any other option to purchase Common Shares from treasury granted as a compensation or incentive mechanism. In addition, the maximum number of Common Shares which may be reserved for issuance to Insiders (which term is defined in the Plan as an “insider” or “associate” of an insider, as such terms are defined in the Securities Act (Ontario)) or which may be issued to an Insider within a one-year period shall be 10% of the issued and outstanding number of Common Shares.

The exercise price of each option shall be determined in the discretion of the directors of the Corporation at the time of the granting of the option, provided that any exercise price may not be less than the market price (being the closing price of the Common Shares as reported by the Toronto Stock Exchange) of the Common Shares at the time of grant.



All options shall be for a term and exercisable from time to time as determined in the discretion of the directors of the Corporation at the time of the grant, provided that no option shall have a term exceeding ten years. Options are not assignable by the optionees except for a limited right of assignment to allow the exercise of options by an optionee's legal representative in the event of death or incapacity.

The Plan provides that the Corporation may arrange for the Corporation or any subsidiary thereof to make loans or provide guarantees for loans by financial institutions to assist eligible optionees to purchase Common Shares

upon the exercise of options. Any such loans granted by the Corporation or any subsidiary thereof shall be full recourse to the optionee and shall be secured by the Common Shares so purchased.

#### **ITEM 7. Major Shareholders And Related-Party Transactions.**

##### **A. Major Shareholders**

To the knowledge of the directors and senior officers of the Corporation, as at the date of this Annual Report, the only person who beneficially owns, directly or indirectly, or exercises control or direction over voting securities of the Corporation carrying more than 5% of the voting rights of the total issued and outstanding shares of the Corporation is as follows:

<b>Name</b>	<b>Number of Voting Securities Owned</b>	
	<b>Common Shares</b>	<b>Percentage of Class</b>
Dr. H.B. Brent Norton	2,421,748	11.2%

Dr. Norton does not have different voting rights from any other stockholder of the Corporation.

Based on information available from Equity Transfer Services, the Corporation's registrar and transfer agent, as of April 30, 2005, there were 22 registered holders of record of the Corporation's common shares in the United States representing 864,545 common shares, or 4.01% of the total common shares issued and outstanding. One of these registered holders is Cede & Co. (the nominee name for The Depository Trust Company), which represents 524 accounts held in the name of a bank, broker or nominee. The number of record holders in the United States is not representative of the number of beneficial holders nor is it representative of where these beneficial holders are residents since many of these ordinary shares were held of record by brokers or other nominees.

##### **B. Related-Party Transactions**

###### *Shareholder Loans*

The following loans have been made to the Named Executive Officers of the Corporation for the purchase of shares in the Corporation. Each loan bears interest at the rate of interest prescribed by the Canada Revenue Agency for employee loans. The interest on these loans is payable annually whereas the principal thereof is payable upon demand. The balances as of December 31, 2004 and April 30, 2005 are as follows:

<b>Name</b>	<b>Date</b>	<b>Total</b>	<b>Total</b>
		<b>Outstanding as of Dec. 31, 2004(\$)</b>	<b>Outstanding as of April 30, 2005(\$)</b>
Michael Evelegh, Ph.D.	Mar-2002	120,000	nil
Total		120,000	nil

##### **C. Interests of Experts and Counsel**

Not Applicable.

#### **ITEM 8. Financial Information.**

***A. Consolidated Statements and Other Financial Information (Audited)***

Refer to Item 18, which contains the following financial statements:

- Consolidated Balance Sheets

- Consolidated Statements of Loss and Deficit
- Consolidated Statements of Cash Flows
- Notes to Consolidated Financial Statements

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

***B.*** ***Significant Changes***

None.

**ITEM 9. *The Offer And Listing.***

***A.*** ***Offer and Listing Details***

1. Indicate the expected price at which the securities will be offered or the method of determining the price, and the amount of any expenses specifically charged to the subscriber or purchaser.

Not Applicable.

2. If there is not an established market for the securities, the document shall contain information regarding the manner of determination of the offering price as well as of the exercise price of warrants and the conversion price of convertible securities, including who established the price or who is formally responsible for the determination of the price, the various factors considered in such determination and the parameters or elements used as a basis for establishing the price.

Not Applicable.

3. If the corporation's shareholders have pre-emptive purchase rights and where the exercise of the right of pre-emption of shareholders is restricted or withdrawn, the corporation shall indicate the basis for the issue price if the issue is for cash, together with the reasons for such restriction or withdrawal and the beneficiaries of such restriction or withdrawal if intended to benefit specific persons.

Not Applicable.

4. The following table sets forth information regarding the price history of the Common Shares on the Toronto Stock Exchange and the American Stock Exchange for the periods indicated.

(a)

for the five most recent full financial years: the annual high and low market prices:

**Fiscal year ended:**

	TSX		Amex	
	High (\$)	Low (\$)	High (\$)	Low (\$)
Dec-04	4.70	2.60	3.40	1.88
Dec-03	4.89	2.41	3.65	2.84
Dec-02	7.15	2.20	-	-
Dec-01	6.00	3.09	-	-
Jan-01	7.00	2.55	-	-

(b) for the most recent full financial years and any subsequent period: the high and low market prices for each full financial quarter:

**Quarter ended:**

	TSX		Amex	
	High (\$)	Low (\$)	High (\$)	Low (\$)
Q1/05	4.14	2.91	3.50	2.35
Jan-Mar				
Q4/04	3.50	2.77	2.83	2.33
Oct-Dec				
Q3/04	4.17	3.00	3.20	2.31
July-Sept				
Q2/04	4.70	2.60	3.40	1.88
Apr-Jun				
Q1/04	4.25	3.60	3.30	2.70
Jan-Mar				
Q4/03	4.70	3.60	3.60	2.84
Oct-Dec				
Q3/03	4.89	2.67	3.65	2.88
July-Sept				
Q2/03	3.00	2.41	-	-
Apr-Jun				
Q1/03	3.25	2.50	-	-
Jan-Mar				

(c) for the most recent six months: the high and low market prices for each month:

	TSX		AMEX	
	High (\$)	Low (\$)	High (\$)	Low (\$)
May-05	3.75	2.92	2.85	2.27
Apr-05	3.94	2.95	3.27	2.40
Mar-05	4.14	3.50	3.50	2.91
Feb-05	3.90	3.01	3.10	2.48
Jan-05	3.15	2.91	2.59	2.35

Dec-04	3.19	2.77	2.58	2.33
Nov-04	3.50	2.96	2.83	2.51

- (d) for pre-emptive issues, the market prices for the first trading day in the most recent six months, for the last trading day before the announcement of the offering and (if different) for the latest practicable date prior to publication of the document.

Not Applicable.

5. State the type and class of securities being offered or listed and furnish the following information:

- (a) Indicate whether the shares are registered shares or bearer shares and provide the number of shares to be issued and to be made available to the market for each kind of share. The nominal par or equivalent value should be given on a per share basis and, where applicable, a statement of the minimum offer price. Describe the coupons attached, if applicable.

Not Applicable.

- (b) Describe arrangements for transfer and any restrictions on the free transferability of the shares.

Not Applicable.

6. If the rights evidenced by the securities being offered or listed are or may be materially limited or qualified by the rights evidenced by any other class of securities or by the provisions of any contract or other documents, include information regarding such limitation or qualification and its effect on the rights evidenced by the securities to be listed or offered.

Not Applicable.

7. With respect to securities other than common or ordinary shares to be listed or offered, outline briefly the rights evidenced thereby.

Not Applicable.

***B. Plan of Distribution***

Not Applicable.

***C. Markets***

The Corporation's Common Shares are traded on the Toronto Stock Exchange under the symbol "IMI" and on the American Stock Exchange under the symbol "IME".

***D. Selling Shareholders***

Not Applicable.



***E. Dilution***

Not Applicable.

***F. Expenses of the Issue***

Not Applicable.

**ITEM 10. *Additional Information.***

**A. *Share Capital***

Not Applicable.

**B. *Memorandum and Articles of Association***

The Corporation previously provided the disclosure to its memorandum and articles of association in response to Item 10.B. of its Registration Statement on Form 20-F (File No. 001-31360) and the Corporation hereby incorporates that disclosure into this Annual Report by reference.

**C. *Material Contracts***

The Corporation is not a party to any material contracts outside of the ordinary course of business.

**D. *Exchange Controls***

There are currently no limitations imposed by Canadian federal or provincial laws on the rights of non-resident or foreign owners of Canadian securities to hold or vote the securities held by such persons in the Corporation. There are also no such limitations imposed by the Corporation's Articles and By-laws with respect to the Common Shares.

*Investment Canada Act*

Under the Investment Canada Act, the acquisition of control by a "non-Canadian" of a Canadian business which carries on most types of business activities (including the business activity carried on by the Corporation) is subject to review in certain circumstances by the Investment Review Division of Industry Canada ("Industry Canada"), a Canadian federal government department, and will not be allowed unless the investment is found by the Minister responsible for Industry Canada likely to be of "net benefit" to Canada. On the other hand, the acquisition of control of a Canadian business which carries on a specific type of business activity, as prescribed, that is related to Canada's cultural heritage or national identity by a non-Canadian is subject to review in certain circumstances by the Department of Canadian Heritage.

Subject to the provisions relating to so-called WTO transactions as described below, an acquisition of control will be reviewable by Industry Canada if the "value of the assets" of the Canadian business for which control is being acquired is (1) \$5 million or more in the case of a "direct" acquisition; (2) \$50 million or more in the case of an "indirect" acquisition, which is a transaction involving the acquisition of the shares of a corporation incorporated outside Canada which owns subsidiaries in Canada; or (3) \$5 million or more but less than \$50 million where the Canadian assets acquired constitute more than 50% of the value of the assets of all entities acquired, if the acquisition is effected through the acquisition of control of a foreign corporation.

These thresholds have been increased respecting the acquisition of control of a Canadian business (1) by investors which are ultimately controlled by nationals of countries which are members of the World Trade Organization ("WTO"), including Americans; or (2) which is a WTO member-controlled (other than Canadian controlled) Canadian business (either, a "WTO transaction"). A direct acquisition in WTO transactions is reviewable only if it involves the direct acquisition of a Canadian business where the value of the assets is \$218 million or more for transactions closing in 2002 (this figure is adjusted annually to reflect the increase in the Canadian nominal gross domestic product at market prices). Indirect acquisitions in WTO transactions are not reviewable unless the value of the Canadian assets acquired constitutes more than 50% of the value of the assets of all entities acquired, in which case the \$218 million threshold applies.

These increased thresholds applicable in WTO transactions do not apply to the acquisition of control of a Canadian business that is engaged in certain sensitive areas such as uranium production, financial services, transportation services or culture businesses.

Even if such acquisition of control is not so reviewable, a non-Canadian must still give notice to Industry Canada of the acquisition of control of a Canadian business within 30 days after its completion.

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*Competition Act (Canada)*

Under the Competition Act, certain transactions are subject to the pre-notification requirements of the Competition Act whereby notification of the transaction and specific information in connection therewith must be provided to the Commissioner of Competition. A transaction may not be completed until the applicable statutory waiting periods have expired, namely 14 days for a short-form filing or 42 days for a long-form filing. Where the parties elect to file a short-form notification, the Commissioner may convert the filing to a long-form, thereby restarting the clock once the parties submit their filing.

A proposed transaction is subject to pre-notification if two thresholds are exceeded. First, the parties and their affiliates must have assets in Canada or gross revenues from sales in, from or into Canada that exceed \$400 million in aggregate value. Having met this first threshold, the parties to a transaction involving a corporation which carries on an “operating business” in Canada must then pre-notify if any one of the following additional thresholds is met: (1) for an acquisition of assets in Canada where the aggregate value of the assets in Canada or the gross revenues from sales in or from Canada generated from those assets exceed \$35 million (the “\$35 million threshold”); (2) in the case of an acquisition of shares of a corporation in Canada or which controls a corporation in Canada where as a result of the proposed acquisition, the person acquiring the shares, together with its affiliates, would own more than 20% (or, if the person or persons making the acquisition already own 20% or more of the voting shares of the target, then 50%) of the voting shares of a corporation that are publicly traded or, in the case of a corporation of which the shares are not publicly traded, the threshold is 35% of the voting shares (and 50% if the person or persons making the acquisition own 35% or more of the voting shares of the subject corporation prior to making the acquisition) and the \$35 million threshold is exceeded; or (3) in the case of a proposed amalgamation of two or more corporations where one or more of the amalgamating corporations carries on an operating business (either directly or indirectly) where the aggregate value of the assets in Canada that would be owned by the continuing corporation resulting from the amalgamation would exceed \$70 million or the gross revenues from sales in or from Canada generated from the assets of the amalgamated entity would exceed \$70 million.

Finally, all merger transactions, regardless of whether they are subject to pre-notification, are subject to the substantive provisions of the Competition Act, namely whether the proposed merger prevents or lessens, or is likely to prevent or lessen, competition substantially in a relevant market in Canada.

***E. Taxation***

This section summarizes the material U.S. federal and Canadian federal income tax consequences of the ownership and disposition of the Common Shares. Nothing contained herein shall be construed as tax advice; you must rely only on the advice of your own tax advisor. The Corporation makes no assurances as to the applicability of any tax laws with respect to any individual investment. This summary relating to the Common Shares applies to the beneficial owners who are individuals, corporations, trusts and estates which:

- for purposes of the U.S. Internal Revenue Code of 1986, as amended, through the date hereof (the “Code”), are U.S. persons and, for purposes of the Income Tax Act (Canada)(the “Income Tax Act”) and the Canada-United States Income Tax Convention (1980), are non-residents of Canada and residents of the U.S. respectively, at all relevant times;
- hold Common Shares as capital assets for purposes of the Code and capital property for the purposes of the Income Tax Act;

- deal at arm's length with, and are not affiliated with, the Corporation for purposes of the Income Tax Act; and
- do not and will not use or hold the Common Shares in carrying on a business in Canada.

Persons who satisfy the above conditions are referred to as "Unconnected U.S. Shareholders."

The tax consequences of an investment in Common Shares by persons who are not Unconnected U.S. Shareholders may differ materially from the tax consequences discussed in this section. The Income Tax Act contains rules relating to securities held by some financial institutions. This Annual Report does not discuss these rules, and holders that are financial institutions should consult their own tax advisors.

This discussion is based upon the following, all as currently in effect:

- the Income Tax Act and regulations under the Income Tax Act;
- the Code and Treasury regulations under the Code;
- the Canada-United States Income Tax Convention (1980);
- the administrative policies and practices published by the Canada Customs and Revenue Agency, formerly Revenue Canada;
- all specific proposals to amend the Income Tax Act and the regulations under the Income Tax Act that have been publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date of this report;
- the administrative policies published by the U.S. Internal Revenue Service; and
- judicial decisions.

All of the foregoing are subject to change either prospectively or retroactively. This summary does not take into account the tax laws of the various provinces or territories of Canada or the tax laws of the various state and local jurisdictions of the U.S. or foreign jurisdictions.

This discussion summarizes the material U.S. federal and Canadian federal income tax considerations of the ownership and disposition of Common Shares. This discussion does not address all possible tax consequences relating to an investment in Common Shares. No account has been taken of your particular circumstances and this summary does not address consequences peculiar to you if you are subject to special provisions of U.S. or Canadian income tax law (including, without limitation, dealers in securities or foreign currency, tax-exempt entities, banks, insurance companies or other financial institutions, persons that hold Common Shares as part of a “straddle,” “hedge” or “conversion transaction,” and Unconnected U.S. Shareholders that have a “functional currency” other than the U.S. dollar or that own Common Shares through a partnership or other pass through entity). Therefore, you should consult your own tax advisor regarding the tax consequences of purchasing Common Shares.

#### *Material U.S. Federal Income Tax Considerations*

Subject to the discussion below regarding Foreign Person Holding Company Rules, Passive Foreign Investment Company Rules and Controlled Foreign Corporation Rules, this section summarizes U.S. federal income tax consequences of ownership and disposition of the Common Shares.

As an Unconnected U.S. Shareholder, you generally will be required to include in income dividend distributions, if any, paid by the Corporation to the extent of the Corporation’s current or accumulated earnings and profits attributable to the distribution as computed based on U.S. income tax principles. The amount of any cash distribution paid in Canadian dollars will be equal to the U.S. dollar value of the Canadian dollars on the date of distribution based on the exchange rate on such date, regardless of whether the payment is in fact converted to U.S. dollars and without reduction for Canadian withholding tax. (For a discussion of Canadian withholding taxes applicable to dividends paid by the Corporation, see “Material Canadian Federal Income Tax Considerations,”) You will generally be entitled to a foreign tax credit or deduction in an amount equal to the Canadian tax withheld. To the extent distributions paid by the Corporation on the Common Shares exceed the Corporation’s current or accumulated earnings and profits, they will be treated first as a return of capital up to your adjusted tax basis in the shares and then as capital gain from the sale or

exchange of the shares.

Dividends paid by the Corporation generally will constitute foreign source dividend income and “passive income” for purposes of the foreign tax credit, which could reduce the amount of foreign tax credits available to you. The Code applies various limitations on the amount of foreign tax credits that may be available to a U.S. taxpayer.

Because of the complexity of those limitations, you should consult your own tax advisor with respect to the availability of foreign tax credits.

With effect from January 1, 2003, for individuals and other taxpayers subject to tax under Section 1 of the Code, the United States reduced the maximum tax rate on certain qualifying dividend distributions to 15% (5% for certain Unconnected U.S. Shareholders). In order for dividends paid by a foreign corporation whose shares are publicly traded (such as the Corporation) to qualify for the reduced rates, (1) the foreign corporation must not be classified as a passive foreign investment company (as defined below) for United State federal income tax purposes either in the taxable year of the distribution or the preceding taxable year, and (2) the Unconnected U.S. Shareholder must hold the underlying shares for at least 60 days during the 121-day period beginning 60 days before the ex-dividend date. Dividends paid by the Corporation on the Common Shares generally will not be eligible for the “dividend received” deduction.

If you sell the Common Shares, you generally will recognize gain or loss in an amount equal to the difference between the amount realized on the sale and your adjusted tax basis in the shares. Any such gain or loss will be long-term or short-term capital gain or loss, depending on whether the shares have been held by you for more than one year, and will generally be U.S. source gain or loss.

Dividends paid by the Corporation on the Common Shares generally will be subject to U.S. information reporting or the 28% backup withholding tax, unless you furnish the paying agent or middleman with a duly completed and signed Form W-9. You will be allowed a refund or a credit equal to any amount withheld under the U.S. backup withholding tax rules against your U.S. federal income tax liability, provided you furnish the required information to the Internal Revenue Service.

#### *Passive Foreign Investment Company Rules*

The passive foreign investment company (“PFIC”) provisions of the Code can have significant tax effects on Unconnected U.S. Shareholders. The Corporation could be classified as a PFIC if, after the application of certain “look through” rules for any taxable year, either:

- 75% or more of the Corporation’s gross income is “passive income,” which includes interest, dividends and certain rents and royalties; or
- the average quarterly percentage, by fair market value of the Corporation’s assets that produce or are held for the production of “passive income,” is 50% or more of the fair market value of all the Corporation’s assets.

To the extent the Corporation owns at least 25% by value of the stock of another corporation, the Corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of such corporation, and as receiving directly its proportionate share of the income of such corporation.

Distributions which constitute “excess distributions” from a PFIC and dispositions of Common Shares of a PFIC are subject to the following special rules: (1) the excess distributions (generally any distributions received by an Unconnected U.S. Shareholder on the shares in any taxable year that are greater than 125% of the average annual distributions received by such Unconnected U.S. Shareholder in the three preceding taxable years, or the Unconnected U.S. Shareholder’s holding period for the shares, if shorter) or gain would be allocated ratably over an Unconnected U.S. Shareholder’s holding period for the shares, (2) the amount allocated to the current taxable year and any taxable year prior to the first taxable year in which the Corporation is a PFIC would be treated as ordinary income in the current taxable year and (3) the amount to each of the other taxable years would be subject to the highest rate of tax on ordinary income in effect for that year and to an interest charge based on the value of the tax deferred during the period during which the shares were owned.





Subject to specific limitations, Unconnected U.S. Shareholders who actually or constructively own marketable shares in a PFIC may make an election under Section 1296 of the Code to mark those shares to market annually, rather than being subject to the above-described rules. Amounts included in or deducted from income under this mark-to-market election and actual gains and losses realized upon disposition, subject to specific limitations, will be treated as ordinary gains or losses. For this purpose, the Corporation believes that the Corporation's shares will be treated as "marketable securities" within the meaning of Section 1296(e)(1) of the Code.

The Corporation believes that it will not be a PFIC for the current fiscal year, that it has not been a PFIC for any prior fiscal year, and it does not expect to become a PFIC in future years; however, because the PFIC determination is made annually on the basis of facts and circumstances that may be beyond its control and because the principles and methodology for determining the fair market values of its assets are unclear, there can be no assurance that the Corporation will not be a PFIC for such years or that the Corporation's determination concerning its PFIC status will not be challenged by the IRS. You should be aware, however, that if the Corporation is or becomes a PFIC, the Corporation may not be able or willing to satisfy record-keeping requirements that would enable you to make a "qualified electing fund" election.

You should consult your tax advisor with respect to how the PFIC rules affect your tax situation.

#### *Controlled Foreign Corporation Rules*

If more than 50% of the voting power or total value of all classes of the Corporation's shares is owned, directly or indirectly, by U.S. shareholders, each of which owns 10% or more of the total combined voting power of all classes of the Corporation's shares, the Corporation could be treated as a controlled foreign corporation ("CFC") under Subpart F of the Code. This classification would require such 10% or greater shareholders to include in income their pro rata shares of the Corporation "Subpart F Income," as defined in the Code. In addition, under Section 1248 of the Code, gain from the sale or exchange of shares by an Unconnected U.S. Shareholder who is or was a 10% or greater shareholder at any time during the five year period ending with the sale or exchange will be ordinary dividend income to the extent of the Corporation's earnings and profits attributable to the shares sold or exchanged.

The Corporation believes that it is not a CFC. However, the Corporation cannot assure you that the Corporation will not become a CFC in the future.

#### *Material Canadian Federal Income Tax Considerations*

This section summarizes the material anticipated Canadian federal income tax considerations relevant to the ownership and disposition of the Common Shares.

Under the Income Tax Act, assuming you are an Unconnected U.S. Shareholder, and provided the Common Shares are listed on a prescribed stock exchange, which includes the Toronto Stock Exchange and the Amex, you will generally not be subject to Canadian tax on a capital gain realized on an actual or deemed disposition of the Common Shares unless you alone or together with persons with whom you did not deal at arm's length owned or had rights to acquire 25% or more of the Corporation's issued shares of any class at any time during the 60-month period before the actual or deemed disposition.

***F. Dividends and Paying Agents***

Not Applicable

***G. Statement by Experts***

Not Applicable

***H. Documents on Display***

The Corporation is subject to the information requirements of the Securities Exchange Act of 1934, as amended, and files reports and other information with the SEC. You may read and copy any of the Corporation's reports and other information at, and obtain copies upon payment of prescribed fees from, the Public Reference Room maintained by the SEC at 100 F Street, NE, Room 1580, Washington, D.C. 20549 and at the SEC's regional offices at Northwestern Atrium Center, 500 West Madison Street, Suite 1400, Chicago, IL 60661. In addition, the SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC at <http://www.sec.gov>. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

The Corporation is required to file reports and other information with the securities commissions in the Canadian provinces of Ontario and Quebec. You are invited to read and copy any reports, statements or other information, other than confidential filings, that the Corporation files with such provincial securities commissions. These filings are also electronically available from the Canadian System for Electronic Document Analysis and Retrieval (SEDAR) (<http://www.sedar.com>), the Canadian equivalent of the SEC's electronic document gathering and retrieval system.

The Corporation "incorporates by reference" information that it files with the SEC, which means that it can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this annual Report on form 20-F and more recent information automatically updates and supersedes more dated information contained by reference in this Annual Report on Form 20-F.

The Corporation will provide without charge to each person, including any beneficial owner, on the written or oral request of such person, a copy of any or all documents referred to above which have been or may be incorporated by reference in this report (not including exhibits to such incorporated information that are not specifically incorporated by reference into such information). Requests for such copies should be directed to the Corporation at the following address: 4211 Yonge Street, Suite 615, Toronto, Ontario, Canada M2P 2A9.

***I. Subsidiary Information***

Not Applicable.

**ITEM 11. *Quantitative and Qualitative Disclosures About Market Risk.***

*Quantitative and Qualitative Information about Market Risk*

The Corporation holds no material financial instruments for trading purposes. Accordingly, the Corporation does not believe that there is any material market risk exposure with respect to derivative or other financial instruments that would require disclosure under this item.

**ITEM 12. *Description Of Securities Other Than Equity Securities.***

Not Applicable.

**PART II**

**ITEM 13. *Defaults, Dividend Arrearages and Delinquencies.***

The Corporation is not currently in a default or delinquent status.

**ITEM 14. *Material Modifications to the Rights of Security Holders and Use of Proceeds.***

The Corporation has not made any material modifications to the rights of security holders.

**ITEM 15. *Controls and Procedures.***

**A. *Disclosure Controls and Procedures***

The Corporation performed an evaluation of the effectiveness of its disclosure controls and procedures that are designed to ensure that the material financial and non-financial information required to be disclosed on Form 20-F and filed with the Securities and Exchange Commission is recorded, processed, summarized and reported timely. Based on our evaluation, which was performed under the supervision and with the participation of our management including the Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), the CEO and CFO have concluded that the Corporation’s disclosure controls and procedures (as defined in Exchange Act Rules 13(a) - 15(e) and 15(d) - 15(e) of the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 20-F are adequate and effective.

**B. *Changes in Internal Controls***

The CEO and CFO have indicated that there have been no significant changes in the internal controls or other factors that could significantly affect internal controls subsequent to the above-mentioned evaluation, nor were there any significant deficiencies or material weaknesses in the Corporation’s internal controls. Accordingly, no corrective actions were required or undertaken.

**ITEM 16. *[RESERVED]***

**ITEM 16A. *Audit Committee Financial Expert***

The Corporation has identified a financial expert to serve as the Chair of the Audit Committee. Mr. David Rosenkrantz is an independent director of the Corporation. His relevant experience includes, but is not limited to, the following:

1. Over 10 years experience in investing as a principal in private companies as Chairman of Patuca Corporation, a merchant banking company
2. Over 7 years experience in investing in and bringing to the public markets junior, high-growth companies
3. Controlling shareholder of several private corporations
4. Chief Compliance Officer of Patuca Securities Limited, a Limited Market Dealer in Ontario, as defined and regulated by the Ontario Securities Commission

5. Former Chief Compliance Officer for Patuca Securities Inc. (now, Kingsdale Capital Markets Inc.), regulated by the Investment Dealers Association and the Ontario Securities Commission, and
6. Over 10 years serving as a director on various public company boards, including work chairing and participating on several audit committees

#### **ITEM 16B. Code of Ethics/Code of Business Conduct**

The Corporation adopted a Code of Business Conduct and has previously provided the disclosure on Form 20-F filed on June 23, 2004 (File No. 001-31360). The Corporation hereby incorporates that disclosure into this Annual Report by reference.

#### **ITEM 16C. Principal Accountant Fees and Services**

##### *Fees and Services*

The table below summarizes the fees (expressed in Canadian dollars) paid by the Company and its consolidated subsidiaries during each of 2003 and 2004.

	2003		2004	
	Amount	%	Amount	%
Audit Fees	\$ 112,433	91.6	115,505	44.5
Audit-Related Fees	-	-	127,110	48.9
Tax Fees <sup>(1)</sup>	10,280	8.4	17,205	6.6
All Other Fees	-	-	-	-
<b>Total</b>	<b>122,713</b>	<b>100.0</b>	<b>259,820</b>	<b>100.0</b>

(1) "Tax fees" are for professional services rendered by our auditors for tax compliance, tax advice on actual or contemplated transactions and tax consulting associated with international transfer prices.

##### *Audit Committee's pre-approval policies and procedures*

The audit committee of the Corporation's board of directors chooses and engages independent auditors to audit the Corporation's financial statements. In 2003, the audit committee also adopted a policy requiring management to obtain the audit committee's approval before engaging the independent auditors to provide any other audit or permitted non-audit services to the Corporation or its subsidiaries. This policy, which is designed to assure that such engagements do not impair the independence of the Corporation's auditors, requires the audit committee to pre-approve audit and non-audit services that may be performed by the auditors.

On a quarterly basis, the Corporation informs the audit committee of the pre-approved services actually provided by the auditors. Services of a type that are not pre-approved by the audit committee require pre-approval by the audit committee's chairman on a case-by-case basis. The chairman of the audit committee is not permitted to approve any engagement of the Corporation's auditors if the services to be performed either fall into a category of services that are not permitted by applicable law or the services would be inconsistent with maintaining the auditors' independence.

#### **ITEM 16D. Exemptions from the Listing Standards for Audit Committee**

Not applicable.

#### **ITEM 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchases**

Not applicable.

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**PART III**

**ITEM 17. *Financial Statements.***

Not Applicable.

**ITEM 18. *Financial Statements.***

The Corporation has previously filed its fiscal 2004 consolidated financial statements and notes to the consolidated financial statements under Form 6-K on April 4, 2005 (File No. 001-31360) and hereby incorporates such documents herein by reference.



**ITEM 19. Exhibits.**

- 1.1 Articles of Amalgamation of the Corporation. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 1.2 By-laws of the Corporation. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 4.1\* Supply Agreement by and between the Registrant and Diagnostic Chemicals Limited dated June 19, 2001. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 4.2\* Cholesterol 1,2,3 - Skin Cholesterol Measurement System - Product Development, Manufacturing and Marketing and Sales Agreement by and between the Registrant and X-Rite, Inc. dated May 14, 1999. Previously filed as an exhibit to the Corporation's Registration Statement on Amendment No. 1 to the Form 20-F filed on October 28, 2002 (File No. 001-31360).
- 4.3 Employment Agreement by and between the Registrant and Ronald Hosking dated Feb. 4, 1998. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 4.4 Employment Agreement by and between the Registrant and Dr. H.B. Brent Norton dated Jan. 1, 2001. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 4.5 Employment Agreement by and between the Registrant and Michael Eveleigh dated Jan 1, 2001. Previously filed as an exhibit to the Corporation's Registration Statement on Amendment No.1 to the Form 20-F filed on October 28, 2002 (File No. 001-31360).
- 4.6 Lease Agreement by and among the Registrant, and 448048 Ontario Inc. dated November 19, 2004.
- 4.7\* Research and Development and Use of Space Agreement by and between McMaster University and the Registrant dated October 31, 2000. Previously filed as an exhibit to the Corporation's Registration Statement on Amendment No.2 to the Form 20-F filed on December 30, 2002 (File No. 001-31360).
- 4.8\* License, Development and Supply Agreement between McNeil PDI Inc. and the Registrant dated May 9, 2002. Previously filed as an exhibit to the Corporation's Registration Statement on Amendment No. 4 to the Form 20-F filed on March 7, 2003 (File No. 001-31360).
- 4.9\* Amendment to License, Development and Supply Agreement by and between McNeil PDI Inc. and the Registrant dated December 20, 2002. Previously filed as an exhibit to the Corporation's Registration Statement on Amendment No. 4 to the

Form 20-F filed on March 7, 2003 (File No. 001-31360).

- 4.10\* License, Development and Supply Agreement by and between McNeil PDI Inc., McNeil Consumer & Specialty Pharmaceuticals Division of McNeil-PPC, Inc., IMI International Medical Innovations Inc. (Switzerland) and the Registrant, dated May 28, 2004. Previously filed as an exhibit to a 6K filed on June 9, 2004 (File No. 001-31360)
- 4.11 Code of Ethics/Code of Business Conduct previously filed as an Exhibit to the Corporation's Registration Statement on Form 20-F filed on June 4, 2003 (File No. 001-31360)
- 4.12 Fiscal 2004 consolidated financial statements and notes to the consolidated financial statements previously filed under Form 6-K on April 4, 2005 (File No. 001-31360)

- 12.1 Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act.
- 12.2 Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act.
- 13.1 Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act.

\* Certain confidential information contained in this exhibit, marked by brackets with asterisks, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

**SIGNATURE**

IMI International Medical Innovations Inc., hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

IMI INTERNATIONAL MEDICAL INNOVATIONS INC.

**By:**  
**Its:**

/s/ RONALD HOSKING  
**Ronald Hosking**  
**Vice President, Finance and Chief**  
**Financial Officer**

**Date: June 29, 2005**