

IMI INTERNATIONAL MEDICAL INNOVATIONS INC  
Form 20-F  
June 23, 2004

As filed with the Securities and Exchange Commission on June 23, 2004

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**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, 2003**

**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)**

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

**Title of each class**

**Name of each exchange on which registered**

Common Shares

The American Stock Exchange  
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: 21,260,902 as of December 31, 2003.

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

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 17  Item 18

(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.

Yes  No

---

---

## TABLE OF CONTENTS

## PART I

<u>IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u>	1
<u>OFFER STATISTICS AND EXPECTED TIMETABLE</u>	1
<u>KEY INFORMATION</u>	1
<u>Currency and Exchange Rates</u>	1
<u>Selected Financial Data</u>	1
<u>Capitalization and Indebtedness</u>	3
<u>Reasons for the Offer and Use of Proceeds</u>	3
<u>Risk Factors</u>	3
<u>INFORMATION ON THE CORPORATION</u>	7
<u>History and Development of the Corporation</u>	7
<u>Business Overview</u>	7
<u>Organizational Structure</u>	35
<u>Property, Plants and Equipment</u>	35
<u>OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u>	35
<u>Operating Results</u>	36
<u>Liquidity and Capital Resources</u>	38
<u>Tabular Disclosure of Contractual Commitments</u>	39
<u>Research and Development</u>	39
<u>Trend Information</u>	41
<u>Off-Balance Sheet Arrangements</u>	41
<u>DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u>	41
<u>Directors and Senior Management</u>	41
<u>Compensation</u>	44
<u>Board Practices</u>	46
<u>Employees</u>	48
<u>Share Ownership</u>	48
<u>MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u>	49
<u>Major Shareholders</u>	49
<u>Related Party Transactions</u>	50
<u>Interests of Experts and Counsel</u>	50
<u>FINANCIAL INFORMATION</u>	50
<u>Consolidated Statements and Other Financial Information (Audited)</u>	50
<u>Significant Changes</u>	50
<u>THE OFFER AND LISTING</u>	51
<u>Offer and Listing Details</u>	51
<u>Plan of Distribution</u>	53
<u>Markets</u>	53
<u>Selling Shareholders</u>	53
<u>Dilution</u>	53
<u>Expenses of the Issue</u>	53

<u>ADDITIONAL INFORMATION</u>	54
<u>Share Capital</u>	54
<u>Memorandum and Articles of Association</u>	54
<u>Material Contracts</u>	54
<u>Exchange Controls</u>	54
<u>Taxation</u>	55
<u>Dividends and Paying Agents</u>	59
<u>Statement by Experts</u>	59
<u>Documents on Display</u>	59
<u>Subsidiary Information</u>	59
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	60
<u>Quantitative and Qualitative Information about Market Risk</u>	60
<u>DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	60
<b>PART II</b>	
<u>DEFAULTS, DIVIDEND, ARREARAGES AND DELINQUENCIES</u>	60
<u>MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS</u>	60
<u>CONTROLS AND PROCEDURES</u>	60
<u>AUDIT COMMITTEE FINANCIAL EXPERT</u>	60
<u>CODE OF ETHICS</u>	61
<u>PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	61
<u>EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	61
<u>PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	61
<b>PART III</b>	
<u>FINANCIAL STATEMENTS</u>	62
<u>FINANCIAL STATEMENTS</u>	62
<u>EXHIBITS</u>	91

**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.

**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, 2004 was \$0.7317.

	2003	2002	2001	2000	1999	
Average	.7136	.6368	.6457	.6732	.6730	
	May-04	Apr-04	Mar-04	Feb-04	Jan-04	Dec-03
Low	.7158	.7293	.7418	.7439	.7496	.7460
High	.7364	.7637	.7635	.7629	.7880	.7738
Average	.7252	.7452	.7527	.7519	.7717	.7617

**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, 2003, December 31, 2002 and the 11-month period ended December 31, 2001 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 the 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 8 to the audited consolidated financial statements included in this Annual Report.

	Fiscal Year ended December 31, 2003	Fiscal Year ended December 31, 2002	11-month period ended December 31, 2001(1)	Fiscal Year ended January 31, 2001	Fiscal Year ended January 31, 2000
<b>Canadian GAAP:</b>					
<b>Operating Results</b>					
Net sales	nil	nil	nil	nil	Nil
Investment tax credits	\$ 223,146	\$ 189,908	\$ 131,000	\$ 115,239	\$ 381,094
Interest income	\$ 275,322	\$ 257,407	\$ 386,580	\$ 522,832	\$ 38,906
Net loss	\$ 4,062,711	\$ 4,018,262	\$ 3,245,206	\$ 1,833,205	\$ 1,332,447
Net loss per share:					
basic and diluted loss per share	\$ 0.19	\$ 0.20	\$ 0.17	\$ 0.11	\$ 0.10

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, 2003	Fiscal Year ended December 31, 2002	11-month period ended December 31, 2001
<b>U.S. GAAP:</b>			
<b>Operating Results</b>			
Net loss	\$ 3,949,318	\$ 4,871,140	\$ 4,162,580
Net loss per share:			
basic and diluted loss per share	\$ 0.19	\$ 0.24	\$ 0.22

	As at December 31, 2003	As at December 31, 2002	As at December 31, 2001	As at January 31, 2001	As at January 31, 2000
<b>Canadian GAAP:</b>					
<b>Financial Position</b>					
Total assets	\$ 8,074,027	\$ 11,379,383	\$ 9,343,958	\$ 11,097,548	\$ 1,396,211
Long-term debt	nil	nil	nil	nil	Nil
<b>Shareholders' Equity</b>					
Total shareholders' equity (net assets)	\$ 7,438,279	\$ 10,689,828	\$ 8,948,696	\$ 10,605,574	\$ 1,134,878
Capital stock	\$ 24,780,846	\$ 23,785,884	\$ 18,212,490	\$ 16,934,162	\$ 5,630,261
Weighted average number of common shares outstanding	20,967,677	20,406,733	19,097,390	17,376,342	13,204,758
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:

U.S. GAAP:	As at December 31, 2003	As at December 31, 2002	As at December 31, 2001
<b>Financial Position</b>			
Total assets	\$ 7,620,454	\$ 10,812,417	\$ 8,635,250
Long term debt	nil	nil	Nil
<b>Shareholders' Equity</b>			
Total shareholders' equity (net assets)	\$ 6,984,706	\$ 10,122,862	\$ 8,239,988
Capital stock	\$ 28,789,296	\$ 28,399,039	\$ 22,850,029

**B. 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 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. In that case 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 to one or more partners, such as major diagnostic or pharmaceutical companies. On May 10, 2002, as amended, the Corporation announced that it has signed an agreement with McNeil Consumer Healthcare (McNeil), a Johnson & Johnson company, to market and distribute the Corporation's skin cholesterol tests in Canada and for the insurance laboratory field in the United States and Mexico. Subsequent to the December 31, 2003 yearend, on May 28, 2004, the Corporation announced an additional agreement with McNeil for the worldwide marketing rights to the skin cholesterol tests. There can, however, be no assurance that such efforts will be successful. If the Corporation relies on third parties to market its products, the commercial success of such products may be outside of its control. Moreover, there can be no assurance that providers, payers or patients will accept the Corporation's products, even if the Corporation's products prove to be safe and effective and are allowed for marketing by the Canadian Health Products and Food Branch (HPB), the U.S. Food and Drug Administration (FDA) and other regulatory authorities. The Corporation's ability to achieve significant market share for each of its products could be affected by reimbursement difficulties with government agencies and third-party insurers, which could hamper the speed with which 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.

*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 eventual commercial sale. Currently, the Corporation's skin cholesterol products are manufactured by Diagnostic Chemicals Limited (DCL) and Southmedic Inc., and X-Rite, Inc. supplies the color measurement instrument used in connection with the tests. The Corporation has not experienced any material problems, such as disruptions of supply, with these manufacturers to date. 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. See Information on the Corporation Business Overview.

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

*The Corporation is not currently generating revenues and if the Corporation is unable to generate revenues and become profitable in the near future, its business will fail.*

To date, the Corporation has not generated significant 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 government grants and Canadian federal and provincial refundable scientific investment tax credits (ITCs) in its annual operating results. To date, the Corporation has received \$63,820 in government grants and \$1,671,000 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 is a tax credit which can be carried forward and applied against future years' taxable income. The ITC Receivable of approximately \$180,000 as of December 31, 2003, 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 carried forward.

*If the Corporation cannot obtain 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 that revenues from partnering activities and product sales will begin in 2004, its current cash resources will be sufficient to meet its current operating and capital requirements through fiscal 2005. However, the Corporation's future capital requirements will depend on many factors, including revenue from the successful commercial launch of its products, continued progress in diagnostic development programs, pre-clinical and clinical evaluation, time and expense associated with regulatory filings, prosecuting and enforcing its patent claims, and costs associated with obtaining regulatory approvals. If additional financing is required, 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 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 licenses, 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 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. The Corporation has also agreed to indemnify each of The Cleveland Clinic Foundation, St. Michael's Hospital, St. Paul's Hospital, St. Joseph's Hospital, The Hamilton General Hospital, University of California, University Health Network (Princess Margaret Hospital), Hamilton Health Sciences Corporation, University of Wisconsin Medical School, Johns Hopkins University Medical Center, AtheroGenics, Inc. and McNeil Consumer Healthcare under their respective clinical trial and/or 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 to otherwise protect against potential product liability claims could inhibit or prevent the commercialization of products developed by the Corporation. The obligation to pay any product liability claim, or finance the costs of a recall of a product, could have a material adverse effect on the business, financial condition and future prospects of the Corporation.

*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 or 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, Executive Vice President of Clinical and Regulatory Affairs and Vice President Finance and CFO, have been employed by the Corporation for eleven, seven and six years, respectively, and the members of the Corporation's Board of Directors each have been members of the Board for five years or more. While the Corporation believes that it has had success to date in its employee retention, it may not be able to continue to attract and keep its key employees.

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

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 subsidiary are located in either Canada or in Switzerland and similarly, all of the directors and executive officers 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 U.S. 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 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 U.S. 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 U.S.

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

*Intense competition in the 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 Cholesterol 1,2,3<sup>TM</sup> has received regulatory clearance from the FDA and HPB and is CE marked in Europe.

Securing regulatory clearances for the marketing of diagnostics products from the HPB in Canada and the FDA in the U.S. can be a long and expensive process which can delay product development. In this regard, 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 only be for limited applications thereby hindering the ability of the Corporation to widely market a 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 must also be carried out to demonstrate cost-effectiveness for reimbursement purposes. This information is required for either government (Canada or EU) or

third-party insurer purposes (U.S.). Failure to achieve enlistment in reimbursement schedules can have a dramatic impact on a product's market penetration in the professional or laboratory market.

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

*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.**

##### **Trade-marks**

Cholesterol 1,2,3 , ColorectAlert , LungAlert and ColoPath are registered trade-marks of the Corporation. All other trade-marks or service marks appearing in this annual Report 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 has been no indication 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 predictors of disease as well as simpler screening methods, IMI aims to detect people's risk of diseases at the earliest possible stage when they can be more effectively treated, or perhaps prevented altogether.

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

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

The Corporation currently owns patents for coronary artery disease (CAD) risk assessment technology, which is used to measure skin cholesterol for determining an individual's risk of CAD, and has in-licensed the technologies for tests to detect the presence of a marker intended for use in colorectal, lung and other cancers. In addition, the Corporation has patents pending for 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 has also acquired the exclusive rights to a hand-held instrument and software for color measurement for use with skin cholesterol testing in point-of-care applications. The Corporation believes that these innovative technologies will fulfil market needs through their ease-of-use and by contributing to cost-effective patient management.

To acquire these technologies, the Corporation has negotiated agreements with the inventors of the technologies with the objective of building long-term relationships and mutual cooperation. To date, the Corporation has acquired technology rights through a combination of equity participation by the inventors, profit sharing, royalties, up-front payments and commitments for funding ongoing product development expenses. 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.

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

### Product Pipeline

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

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

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

## **Business Strategy**

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

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

### *Ensure a Multiple Product Pipeline*

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

### *Pursue Strategic Relationships*

The Corporation pursues a strategy of building collaborative relationships with leading companies to conduct clinical trials and to assist with the development of its products. The Corporation'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 are considered 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 U.S. and internationally. The Corporation also relies upon trade secrets, non-patented proprietary know-how and continuing technological innovation to develop and maintain its competitive position.

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

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

## **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 caused a dramatic growth in total health care spending. As a result of these increasing expenditures, cost containment strategies are being evaluated and implemented by governments and private payers around the world. Management believes that technologies that help to detect disease early and help reduce health care costs, especially if quality of care is not adversely impacted, should represent a significant market opportunity. Health care cost containment efforts are also shifting treatment focus away from hospitals to less expensive alternative care sites.

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

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

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

Theta Reports 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.

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

In November 2003, the Corporation announced that its skin cholesterol test will be branded in Canada by McNeil Consumer Healthcare (McNeil) as PREVU\* Coronary Heart Disease Predictor (PREVU\*). On May 28, 2004, the Corporation announced an exclusive worldwide licensing agreement with McNeil to market and distribute the skin cholesterol tests through its worldwide affiliations. The agreement applies to all current and future formats of the test, in all fields of use, including the medical, laboratory and home use markets.

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

##### *Skin Cholesterol Pathology*

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

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

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



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

Atherosclerotic plaque results in increased risk for:

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

#### *Market*

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

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

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

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

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

*The Opportunity*

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

*The Technology*

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

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

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

*The Corporation's Cardiovascular Products*

Cholesterol 1,2,3 is a non-invasive test that evaluates the amount of cholesterol accumulated in a patient's epidermis (skin) surface. The test is conducted in three minutes in two separate steps on the palm of the hand. In the first step, a chemical solution consisting of a cholesterol-binding agent and an enzyme, linked together by a synthetic copolymer, is placed on the hand for one minute. This solution binds to the skin's cholesterol-rich surface layer. After one minute the excess solution is blotted dry, leaving only that part of the solution that is bound to epidermal cholesterol. In the second step, an indicator solution, containing a dye in a 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.

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

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

## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

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

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

### *Development History and Clinical Findings*

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

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

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

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

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

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

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

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

In addition, a clinical trial was completed in April 2001 at St. Paul's Hospital at the University of British Columbia, Vancouver, British Columbia, comparing skin cholesterol measurements to other measures of CAD risk, including carotid sonography, flow-mediated brachial vasoactivity, and serum markers. 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 addition to the Cholesterol 1,2,3 product, the Corporation is advancing development of laboratory-processed and consumer formats of the skin cholesterol test and has commenced pilot studies on prototypes of the tests.

## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

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

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

*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.

*Marketing and Distribution*

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

The amended agreement provides McNeil with exclusive rights, in these fields and in this territory, to the present and future versions of the Corporation's skin cholesterol tests, which are being jointly developed by McNeil and the Corporation. The agreement has a 15-year term and requires McNeil to purchase the Corporation's skin cholesterol-based tests and pay ongoing royalties to the Corporation on sales, in addition to a series of milestone payments, which will be based on the licensed products. The Corporation may terminate this agreement if certain minimum levels of sales of the skin cholesterol test are not met. On May 28, 2004 the Corporation expanded its relationship with McNeil and signed an exclusive worldwide licensing agreement for the Corporation's skin cholesterol-based cardiac risk prediction tests. These products will be marketed by McNeil and its worldwide affiliates under the brand name PREVU\* Coronary Heart Disease Predictor. This agreement has a minimum term of 10 years. Under the financial terms of the agreement, the Corporation receives a \$3.0 million up front payment as well as a series of milestone payments of up to \$15.75 million in addition to sales and royalties. Since future royalty rates, royalties and milestone payments under this agreement are based on specific sales targets, the Corporation is unable at this time to accurately predict the aggregate future payments that could be received under this agreement.

*Patents*

The Corporation has obtained patents that cover the chemical formulations for the reagents employed in skin cholesterol testing as well as a method of using the same reagents for the visual indication of cholesterol on 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. A notice of allowance was received in the U.S. in 2002.

In May 1998, the Corporation acquired the worldwide patent rights for a method for determining skin cholesterol through the use of biosensor devices. In April 2002, the Corporation was granted this patent in the U.S. It is currently pending in Europe, Canada and Japan. The Corporation has filed a patent 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 2003, the Corporation was granted a new patent in the U.S. titled [Multi-layer Analytical Elements](#) , which further protects the technology. In April 2004, the Corporation filed a patent application for its lab-processed skin cholesterol test with the U.S. Patent and Trademark Office and the Canadian Intellectual Property Office.

#### *Trade-marks*

The Corporation filed a trade-mark 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 trade-mark has been granted in Canada as well as in Europe.

#### *Competition*

The measurement of cholesterol is currently conducted through blood-based analysis. The Corporation is not aware of any other test currently marketed or in development that non-invasively measures skin cholesterol. The Corporation is aware that research has been undertaken using other testing approaches that employ body fluids, such as saliva and tears. The stage of development of such approaches is unknown. See [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 is suitable for use in the physician's office for risk assessment and, perhaps, monitoring applications providing the clinician valuable additional data in an overall patient workup for CAD risk.
- ***Monitoring for drug and dietary therapy.*** Given the ease of use of skin cholesterol testing, the test may be used to monitor the progress of therapy. Thus, pharmaceutical companies may be interested in using or co-marketing this test to ensure patient compliance. (Cholesterol 1,2,3 is not yet cleared for this use.)

- **Pharmacy market.** Tests may be offered through retail pharmacies to consumers. As well, pharmaceutical companies might be interested in using or co-marketing the tests at the pharmacy level as a means of encouraging individuals to see their doctors for cholesterol lowering drug therapies. (The Corporation is currently developing this format.)
- **Screening for insurance risk assessment.** The market for insurance testing represents a significant opportunity for the Corporation's predictive heart disease test throughout North America. Millions of insurance policies are granted every year without the benefit of a cardiovascular disease assessment. In 2002, Americans purchased U.S.\$2.9 trillion of new life insurance coverage.
- **Home testing market.** Tests could be purchased by individuals in a retail pharmacy and self-administered at home to test and monitor skin cholesterol levels. The U.S. cholesterol self-test market is projected to grow from about US\$30 million in 2003 to just under US\$150 million in 2007, driven largely by the introduction of non-invasive measurement products. (*Greystone Associates, Cholesterol Monitoring: Self-Testing Markets and Opportunities, 2003*)

### Colorectal Cancer Tests (ColorectAlert and ColoPath)

#### *Pathology*

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

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

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

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

#### *Colorectal Cancer Screening*

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

- 1 digital rectal examination ( DRE )



- 1 fecal occult blood testing ( FOBT )
- 1 sigmoidoscopy
- 1 double contrast barium enema ( DCBE )

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

#### *Market*

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

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

#### *The Opportunity*

The Corporation's rectal mucus test (ColorectAlert) is a patented technology that detects a carbohydrate marker associated with cancerous and pre-cancerous conditions. Dr. A.K.M. Shamsuddin (the ColorectAlert Inventor) of Baltimore, Maryland developed this technology at the University of Maryland School of Medicine. Pursuant to agreements (the ColorectAlert License Agreement) dated March 27, 1998, May 1, 1998 and October 23, 2001 between the Corporation and the ColorectAlert Inventor, the Corporation acquired a license for all diagnostic applications and products which incorporate or make use of this technology as well as the license for the two existing U.S. patents and one Japanese patent. Pursuant to the terms of the ColorectAlert License 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. As of December 31, 2003, the Corporation has made milestone payments under the ColorectAlert License Agreements of approximately \$328,000. Future milestone payments, upon completion of specific milestones, could amount to as much as \$165,000. In addition, the Corporation granted warrants to purchase up to 100,000 common shares at exercise prices from \$3.50 and \$4.50 per share to the ColorectAlert Inventor in connection with the ColorectAlert License Agreements. See note 6[b][i] to the Financial Statements. The ColorectAlert License Agreements do not provide for a fixed termination date and may only be terminated by the parties in the event of a material breach by the other party.

A second colorectal cancer test, ColoPath, is a patented technology that detects another marker believed to be associated with cancer of the colon or rectum. The technology was developed by Procyon BioPharma Inc. (Procyon). The Corporation entered into an agreement with Procyon dated March 19, 2001, as amended, (the Procyon License Agreement) whereby the Corporation licensed the intellectual property, including patent rights and trade-marks 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. To December 31, 2003, the Corporation has made milestone payments under the Procyon License Agreement of \$125,000. Future milestone payments, upon completion of specific milestones, could amount to as much as \$225,000. In addition, the Corporation granted warrants to purchase up to 75,000 common shares at an exercise price of \$4.50 per share to Procyon in connection with this agreement. The warrants expired on March 19, 2004, unexercised. The Procyon License Agreement does not have a fixed termination date.

#### *The Technologies*

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

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

#### *Development History and Clinical Findings*

The Corporation has conducted clinical trials to validate the ColorectAlert Inventor's data that had been collected on a few thousand patients. In accordance with a sponsored research agreement (the St. Michael's Agreement) dated November 30, 1998, the Corporation completed a prospective clinical trial in December 1999 at St. Michael's Hospital (St. Michael's), Wellesley Central Site, Toronto, Ontario, Canada with Dr. N. 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.

#### *Patents*

The Corporation acquired the rights to two U.S. patents and one Japanese patent for ColorectAlert as well as the rights to worldwide granted patents for ColoPath. A patent involving the spectrophotometric measurement of

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.

#### *Competition*

##### CEA

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

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

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

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

##### FOBT

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

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

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

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

*Key Markets*

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

**Lung Cancer Test (LungAlert)**

*Pathology*

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

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

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

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

Lung cancer stages are:

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

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

*Lung Cancer Screening*

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

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

1. An X-ray is a simple and safe procedure that is relatively ineffective. Less than 40% of all lung cancers can be detected by this screening method.
2. Conventional Sputum Cytology has been used for over 50 years; however it is the least sensitive and only able to identify 20% of lung cancer cases.
3. Spiral CT has been hailed as the technology that holds the greatest promise for cost effectively screening for lung cancer. Although it holds the ability to detect approximately 70% of lung cancers, it has a high cost which translates into \$300-\$600 per test.
4. Positron Emission Tomography is the most accurate screening test available at over 90% sensitivity. Since it is extremely expensive at \$2,500 per patient, widespread use would be unfeasible.
5. Bronchoscopy is used as a final diagnostic option prior to surgery. It is highly invasive and results in a 0.2% mortality rate with the majority of patients unable to return to daily routines for several weeks or months.

#### *Market*

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

#### *The Opportunity*

LungAlert is based on a modified version of the ColorectAlert technology, using a sputum sample instead of a rectal mucus sample. See 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 will be presented in May 2004 at the American Thoracic Society International Conference, a premier global forum for physicians.

In October 2003, the Corporation announced that LungAlert was included in the National Cancer Institute's International Early Lung Cancer Action Program ( 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 computed tomography (CT scan) twice, once at baseline and once at a one-year follow-up. Patients will also be tested with LungAlert at these times. Data from the study will help determine the ability of LungAlert to detect cancers among a high-risk population, and will also provide data on the relationship between LungAlert values and the stage and location of cancer.

#### *Patents*

Patent coverage for LungAlert is the same as patent coverage for ColorectAlert. See [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*)

#### **Prostate Cancer Test**

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

#### **Breast Cancer Test**

##### *Pathology*

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

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

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

Breast cancer is categorized into the following stages:

**Stage 0:**

- Non-invasive carcinoma

**Stage I:**

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

**Stage II:**

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

**Stage III:**

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

**Stage IV:**

- Metastatic cancer

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

*Breast Cancer Screening*

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

*Market*

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

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

### *The Opportunity*

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

### *Development History and Clinical Findings*

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

### *Patents*

Patent coverage for the breast cancer test is the same as patent coverage for ColorectAlert and LungAlert. See [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).

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.

Several tests for breast 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 breast cancer and is currently monitoring their progress. Some of the firms involved in the development of such products are BioCurex Inc., Matritech Inc., Aitairgin Technologies Inc. and Cytex Corporation.

### *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 which 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***Skin Cholesterol*

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Granted	Method for visual indication of cholesterol on skin surface agents used therefore and methods for producing such agents	United States	5,489,510	February 6, 1996	February 6, 2013
Granted	Method for producing affino-enzymatic compounds and visualizing agent and application thereof	United States	5,587,295	December 24, 1996	December 24, 2013
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
Granted	Multilayer Analytical Element	Australia South Korea United States Canada	702663 235211 6,605,440 2,207,555	June 3, 1999 September 21, 1999 August 12, 2003 February 24, 2004	December 14, 2015 December 14, 2015 December 14, 2015 December 14, 2015
Pending	Multilayer Analytical Element	PCT Brazil China Europe Japan Mexico	CA95/00698 PI9510038-5 95197367.3 95940097.9 HE1-8-17984 974469	N/A	N/A
Granted	Method of Determining Skin Tissue Cholesterol	United States	6,365,363	April 2, 2002	January 26, 2018

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

---

Pending	Method of Determining Skin Tissue Cholesterol	PCT Canada Brazil Europe Japan Hong Kong	RU98/00010 2281769 PI98707594-2 98901608.4 10-5396529 00105898.2	N/A	N/A
---------	--	---	---	-----	-----

---

*Skin Cholesterol*

Patent Status	Title	Jurisdiction	Patent Number	Grant Date	Expiry Date
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays  <i>As it pertains of Skin Cholesterol Measurement</i>	PCT Australia Brazil China Europe Russia Hong Kong India Japan Mexico	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A	N/A
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays  <i>As it Pertains to Skin Cholesterol Measurement</i>	United States	09/830,708	N/A	N/A
Pending	Direct Assay of Cholesterol in Skin Samples Removed by Tape Stripping	Canada  United States		N/A	N/A

*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	November 19, 2009
Granted	Screening Test and Kit for Cancerous and Precancerous Conditions	USA	5,348,860	September 20, 1994	September 20, 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 Mexico	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A	N/A
Pending		USA	09/830,708	N/A	N/A

Spectrophotometric  
Measurement in  
Colour-Based Biochemical  
and Immunological Assays

*As it Pertains to Cancer  
Detection*

---

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

**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	Japan	2000-581456	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Brazil	PI19915005	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Israel	139545	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Mexico	012243	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	Korea	2001-7005707	N/A	N/A
Pending	Screening Test for the Early Detection of Colorectal Cancer	India	INPCT/2001/00591	N/A	N/A
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	USA	5,416,025	May 16, 1995	November 29, 2013
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Europe	0731914	November 23, 1994	November 23, 2014
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	France	0731914	April 18, 2001	November 23, 2014

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Spain	ES 2155513	April 18, 2001	November 23, 2014
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
Granted	Screening Test for the Early Detection of Colorectal Neoplasia	Japan	514,718/95	December 26, 2003	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***

<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 and Kit for Cancerous and Precancerous Conditions	USA	5,348,860	September 20, 1994	September 20, 2011
Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays  <b><i>As it Pertains to Cancer Detection</i></b>	PCT Australia,Brazil China Europe Russia Hong Kong India,Japan Mexico	PCT/CA00/00918 66734/00 PI0013096.6 00813497.9 00954181.4 RU 2002103517 0310671.6 PCT/2002/00307 2001 515964	N/A	N/A

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

Pending	Spectrophotometric Measurement in Colour-Based Biochemical and Immunological Assays <i>As it Pertains to Cancer Detection</i>	USA	09/830,708	N/A	N/A
---------	---	-----	------------	-----	-----

---

***Prostate Cancer***

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

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.



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

### **Competition**

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

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

Competitors of the Corporation may: (i) use different technologies or approaches to develop products similar to products which the Corporation is seeking to develop; (ii) develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any developed by the Corporation; and (iii) succeed in obtaining regulatory approval of such products before the Corporation obtains approval of its products. There can be no assurance that the Corporation's products will compete successfully or that research and development will not render the Corporation's products obsolete or uneconomical. See 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 Corporation's marketing partner for Canada and select U.S. markets, McNeil Consumer Healthcare, commenced an education and awareness program in the fall of 2003 and expects to make the skin cholesterol technology available in 2004. The other technologies of the Corporation are in various stages of clinical trials in the U.S. and Canada, and thus the timing for receipt of HPB and FDA clearance is uncertain. Generally, research and clinical data used to receive regulatory approval in one jurisdiction may be used for regulatory submissions in other jurisdictions.

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

**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 provide key man insurance coverage.

**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 and is currently negotiating a new lease for these premises. The Corporation also occupies laboratory facilities at McMaster University in Hamilton, Ontario, Canada under an agreement that expires on October 31, 2005.

All assets are held in the name of the Corporation. The following table details the Corporation's fixed assets as of December 31, 2003:

	Cost (\$)	Accumulated Depreciation (\$)	Net Book Value (\$)
Computer equipment	192,671	111,659	81,012
Furniture and equipment	55,802	38,936	16,866
Research instrumentation	568,753	282,587	286,166
Laboratory equipment	25,456	9,197	16,259
Leasehold improvements	8,705	5,803	2,902
<b>TOTAL</b>	<b>851,387</b>	<b>448,182</b>	<b>403,205</b>

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

The following section should be read in conjunction with the Corporation's audited financial statements and notes thereto for the year ended December 31, 2003, December 31, 2002 and the 11-month period ended December 31, 2001, which have been prepared in accordance with Canadian GAAP and which are included in Item 18. There are significant differences between Canadian GAAP and U.S. GAAP, which are described and reconciled in note 8 to the audited financial statements for the year ended December 31, 2003. Some of the statements contained in this section 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 express or implied by such forward-looking statements.

**Overview**

The Corporation is a predictive medicine company that develops and commercializes rapid, non-invasive tests for the early detection of life-threatening diseases, particularly cardiovascular disease and cancer. To date, the Corporation has developed and/or acquired several technologies, including a test to measure skin cholesterol (Cholesterol 1,2,3), as well as the technologies for tests to detect the presence of a carbohydrate marker intended for use in colorectal, lung and other cancers. In addition, the Corporation has patents pending for color measurement in biological reactions and has a right of first refusal on certain cancer-related technologies in the predictive medicine field.

The Corporation seeks to find proprietary technologies that have demonstrated some clinical efficacy in human testing and then completes the final development in preparation for clinical trials. The Corporation seeks marketing and sales partnerships with multinational diagnostic, pharmaceutical and consumer goods companies to distribute its products.



## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

From its inception on November 9, 1992 through December 31, 2003, the Corporation has incurred losses totaling \$17,655,000 and has earned no significant revenues to date. However, management of the Corporation believes that substantial revenues and profits will be generated in the future following additional regulatory approvals and commercialization of the technologies.

In December 2001, the Corporation changed its year-end from January 31 to December 31. This change resulted in an 11-month fiscal year ended December 31, 2001.

### A. *Operating Results*

#### *Year Ended December 31, 2003 Compared To 2002*

The consolidated loss for the year ended December 31, 2003 was \$4,063,000 (\$0.19 per share) compared to \$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 to \$2,105,000 for fiscal 2002. Clinical trial expenses, which consist principally of fees paid to third parties, decreased by approximately \$330,000 for the year, compared to 2002. This resulted from changes both in the mix and timing of the trials. The Corporation is currently conducting at least 15 clinical trials, 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 will 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. See note 2 to the Corporation's consolidated financial statements. The stock-based compensation costs that related to research and development amounted to a non-cash expense of \$189,000 compared to \$82,000 for 2002.

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

Amortization expenses for 2003 amounted to \$281,000 compared to \$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 scientific research tax credits (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 \$275,000 compared to \$257,000 for 2002, an increase of \$18,000 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 to \$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 to \$995,000 in 2002 when 206,000 performance-

## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

based options vested. For a detailed reconciliation of consolidated financial results from Canadian GAAP to U.S. GAAP, refer to note 8, Reconciliation of Canadian to U.S. Generally Accepted Accounting Principles .

For U.S. GAAP purposes the Corporation is considered a development-stage company. Therefore, U.S. GAAP requires additional information about the financial operations of the Corporation. This information is disclosed in note 8(h) to the consolidated financial statements.

### *Year Ended December 31, 2002 Compared To 11 Months Ended December 31, 2001*

The consolidated loss for the year ended December 31, 2002 ( fiscal 2002 ) was \$4,018,000 (\$0.20 per share) compared to \$3,245,000 (\$0.17 per share) for the 11 months ended December 31, 2001 ( fiscal December 2001 ).

Although the Corporation received its first revenues in fiscal 2002 in the form of \$100,000 in license fees from McNeil Consumer Healthcare, the payment was recorded as deferred revenue on the balance sheet and will be amortized over the remaining term of the agreement (approximately 14.5 years).

Research and development expenditures for fiscal 2002 increased to \$2,105,000, compared to \$2,047,000 for fiscal December 2001. Clinical trial expenses, which consist principally of fees paid to third parties, decreased by approximately \$435,000 for the year, compared to fiscal December 2001. This resulted from reduced clinical activity related to Cholesterol 1,2,3 following the FDA submission in 2001 (and subsequent clearance in 2002) and the reallocation of resources to the development of a second generation version of the test. Compensation expense increased by approximately \$280,000 during the period resulting, in part, from incentive payments related to achieving regulatory and product development milestones as well as from an increase in headcount to support the development of the new consumer skin cholesterol test and the ongoing development of the cancer program. In addition, on January 1, 2002, the Corporation adopted the accounting for stock-based compensation for non-employees and stock granted to employees, using the fair value method. The stock-based compensation costs that related to research and development amounted to a non-cash expense of approximately \$57,000 for fiscal 2002. The cost of registering intellectual property increased by \$148,000 over fiscal December 2001 as the Corporation continued to solidify its patent position on its cholesterol and cancer technologies. The Corporation expects to continue its research and development program at these levels for the near future as it develops new products and expands the clinical applications of its current product lines.

General and administration expenses amounted to \$2,141,000 for fiscal 2002, compared to \$1,500,000 for fiscal December 2001, an increase of \$641,000. Professional fees related to the preparation of the U.S. SEC registration application amounted to approximately \$260,000 for fiscal 2002 compared to nil in fiscal December 2001. SEC registration was cleared subsequent to the year-end, in March 2003. Other professional fees, including consulting and legal expenses related to the completion of a marketing agreement, increased by \$86,000 for the year. Shareholder communications and investor relations costs increased by \$67,000 over fiscal December 2001 in support of developing an awareness for the Corporation in the U.S. Compensation expense increased by \$157,000 for fiscal 2002 compared to fiscal December 2001 resulting from the addition of one employee and from employee incentive payments for the achievement of milestones. The adoption of stock-based compensation in fiscal 2002 applied to the Employee Share Purchase Plan and resulted in a non-cash expense of \$36,000 for the year.

Amortization expenses for fiscal 2002 amounted to \$219,000 compared to \$215,000 for the 11 months in fiscal December 2001. Of the fiscal 2002 expense, \$77,000 was amortization on capital equipment and \$142,000 was amortization on acquired technologies (\$89,000 and \$126,000, respectively in fiscal December 2001). Additions of capital equipment during fiscal 2002 and fiscal December 2001 amounted to \$21,000 and \$190,000, respectively.

Recoveries of provincial scientific research tax credits (ITCs) amounted to \$190,000 for the year. This includes an accrual of \$140,000 for fiscal 2002. In 2001 management recorded its best estimate of the recovery for the year. In 2002, the actual recovery for 2001 exceeded management's estimate by \$50,000.

Interest income decreased from \$387,000 in fiscal December 2001 to \$257,000 in fiscal 2002. In spite of an increase in invested cash, a continuing decline in market interest rates in fiscal 2002 resulted in a lower return on investments.

U.S. GAAP

For purposes of U.S. GAAP, the consolidated loss for fiscal 2002 was \$4,871,000, compared to \$4,163,000 for fiscal December 2001. For fiscal 2002, acquired technology expense was nil compared to \$687,000 for fiscal December 2001 which resulted from the purchase of technologies related to the Corporation's research activities in the area of cancer detection. It was expensed at the time of acquisition in fiscal December 2001 for U.S. GAAP but capitalized under Canadian GAAP and amortized over its expected useful life.

The adjustment for stock and stock option compensation expense for U.S. GAAP, in addition to the Canadian GAAP expense recognized, amounted to \$995,000 for fiscal 2002. This included \$931,000 relating to 206,350 performance stock options issued to employees that vested during the period. The performance criteria that were met included regulatory clearance of Cholesterol 1,2,3 and the signing of a marketing partner for the product. For fiscal December 2001, the stock and stock option compensation expense for performance options amounted to \$255,000, based on 94,125 options that vested. For a detailed reconciliation of consolidated financial results from Canadian GAAP to U.S. GAAP, refer to note 8, Reconciliation of Canadian to U.S. Generally Accepted Accounting Principles .

**B. Liquidity and Capital Resources**

As at December 31, 2003 the Corporation had cash, cash equivalents and short-term investments totaling \$6,697,000 (\$10,112,000 as at December 31, 2002). The Corporation invests its funds in short-term financial instruments and marketable securities. During fiscal 2003, the Corporation received \$238,070 from the exercise of options, which were previously granted pursuant to the Corporation's stock option plan. Cash used to fund the operating activities during the year amounted to \$3,396,000 compared to \$3,550,000 in 2002. The Corporation has no long-term debt.

Total assets decreased by \$3,305,000 to \$8,074,000 as at December 31, 2003, from \$11,379,000 at December 31, 2002. [This resulted primarily from the loss for the year][Elaborate]

The Corporation's lease for its office premises expires on June 30, 2005 and the future minimum annual lease payments under the lease amount to \$78,000 for 2004 and \$31,000 for 2005. The Corporation is currently negotiating a new lease for the premises.



**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	\$ 982,000	\$ 556,000	\$ 426,000	-
Research Agreements	\$ 210,000	\$ 120,000	\$ 90,000	-
Other	\$ 39,000	\$ 39,000	-	-
Total	\$ 1,231,000	\$ 715,000	\$ 516,000	-

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

To date, the Corporation has financed its activities through the issuance of shares and the recovery of ITCs. The Corporation believes that its existing cash resources together with the Investment Tax Credits Receivable of \$180,000 will be sufficient to meet its current operating and capital requirements until fiscal 2005 and that no additional funds would be required to support ongoing product development, research and clinical trials. However, the Corporation's future capital requirements will depend on many factors, including continued progress in diagnostic development programs, pre-clinical and clinical evaluation, time and expense associated with regulatory filings, prosecuting and enforcing its patent claims and costs associated with obtaining regulatory approvals. In order to commercialize its products, the Corporation plans to extend the out-licensing of the sales and marketing rights to its products.

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 2003, the Corporation spent \$1,919,000 on Corporation-sponsored research and development activities, compared to \$2,105,000 and \$2,047,000 in 2002 and in the 11 months ended December 2001.

Below is a summary of the Corporation's products and the related stages of development 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."

Product	Description / Indication	Phase of Development	Approx. % Completed	Collaborator	Estimate of Completion of Phase
<b><u>Coronary Artery Disease (CAD) Risk Assessment Technology:</u></b>					
Cholesterol 1,2,3	Point of care skin cholesterol test that provides information about an individual's risk of coronary artery disease	Regulatory clearance in Canada, U.S. and Europe;	100%	McNeil Consumer Healthcare; Various clinical trial sites	2003
		Additional clinical trials to expand claims	50%		2005
Lab-Processed Test	Lab-processed skin cholesterol test risk of CAD	Prototype completed; Patent pending; Clinical trials; Commercial launch in select markets	80%	McNeil Consumer Healthcare	2004
Consumer (Home) Test	Consumer version of the skin cholesterol test	Prototype completed; Validation & clinical trials	50%	McNeil Consumer Healthcare	2005
<b><u>Cancer Technologies:</u></b>					
ColorectAlert & Colopath	Mucus tests for early detection of colorectal cancer	2,000 patients tested in clinical trials; additional trials required for regulatory clearance	60%	St. Michael's Hospital	2005
LungAlert	Sputum test for early detection of lung cancer	Optimization of test procedures; 650 patients tested in clinical trials; expand clinical trials; publish scientific papers	60%	St. Joseph's Hospital; I-ELCAP	2005
Breast Cancer Test	Aspirate test for early detection of breast cancer	100 patients tested in clinical trials; Optimization of test procedures; expand clinical trials	50%	M.D. Anderson Cancer Center	2006

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, 2003 and 2002, the 11-month period ended December 31, 2001, and the year ended January 31, 2001.

## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

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 Ended Dec. 31, 2003	Fiscal Year Ended Dec. 31, 2002	11-Month Period Ended Dec. 31, 2001	Fiscal Year Ended Jan. 31, 2001	Historical Cumulative total since Feb. 1, 1997
CAD Risk Assessment Technologies	\$ 860,000	\$ 1,188,000	\$ 1,297,000	\$ 603,000	\$ 5,066,000
ColorectAlert and ColoPath	\$ 327,000	\$ 495,000	\$ 488,000	\$ 445,000	\$ 2,377,000
LungAlert	\$ 228,000	\$ 178,000	\$ 118,000	\$ 50,000	\$ 574,000
Breast Cancer	\$ 45,000	-	-	-	\$ 45,000

The Corporation expects to generate initial revenues from sales of Cholesterol 1,2,3 in the calendar year 2004. The Corporation anticipates that costs to complete the development and clinical trials of the coronary artery disease technologies will not exceed \$1.5 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 \$1.8 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, 43, President and CEO, Director*

Dr. Norton founded IMI 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, London, Ontario Canada.

*Michael Eveleigh, Ph.D., 51, Executive Vice President, Clinical and Regulatory Affairs*



## Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

Dr. Evelegh joined IMI on April 1, 1997 in the position he currently holds as IMI'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 IMI 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, 59, Vice President, Finance and CFO*

Mr. Hosking joined the Corporation on September 25, 1997 in the position he currently holds as IMI'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, 66, 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. Formerly, President of the Canadian Automobile Association, Central Ontario.

*H.B. Brent Norton, MD, MBA, 43, Director*

See description above under Directors, Senior Management and Employees Directors and Senior Management Senior Management.

*John Carroll, BA, MBA, 70, Director*

Mr. Carroll has served as one of the Corporation's directors since June 6, 1994. Mr. Carroll has also served as Director of Clairon Holdings and AXA Insurance Co. Ltd. from 1997 and 1991, respectively, to the present. Prior to that, he was a Director of 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.

*Anthony F. Griffiths, BA, MBA, 73, Director*

Mr. Griffiths has served as one of the Corporation's directors since July 13, 1995. From 1994, 1997 and 2000, respectively, to the present, Mr. Griffiths has served as Director and Chairman of Slater Steel Inc., Russel Metals Inc. and Brazilian Resources Inc. In addition, Mr. Griffiths has been a Director of numerous companies, including Fairfax Financial Holdings Limited from 2002, Burgundy Asset Management from 1990, Vitran Corporation Inc from 1987, ShawCor from 1980, Leitch Technology Corporation from 1994, Alliance Atlantis Communications Inc. from 1996 and Hub International Limited from 1998 to the present. He was also a Director of 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.

*David Rosenkrantz, P. Eng., 46, Director*

Mr. Rosenkrantz has served as one of the Corporation's directors since June 11, 1998. Mr. Rosenkrantz has been President and Director of Patuca Securities Limited since 1993 and is the founding partner of Patuca Corporation, a merchant banking corporation. In addition, Mr. Rosenkrantz has served as Chairman and Director of Stellar International Inc. since 2002, Versent Corporation since 1993, Neuromolecular Inc. since 2001, and as Director of Carfinco Income Fund since 2002. He was also a Director of LymphoSign Inc. from 2000 to 2003, Northern Mountain Helicopter Group Inc. from 1996 to August 2000 and Beta Brands Inc. from 1993 to 1995.

### **SCIENTIFIC ADVISORY BOARD**

The role of the Scientific Advisory Board (the "SAB") is to provide IMI 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. He is also Professor, Ohio State University, Department of Internal Medicine. 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; and (iii) Vice President, Finance and Chief Financial Officer (collectively, the Named Executive Officers ) for the years ended December 31, 2003 and 2002, and the 11-month period ended December 31, 2001:

Name and Position	Financial Year Ended <sup>(1)</sup>	Annual Compensation			Long-term Compensation	All other Compensation <sup>(2)</sup> (\$)
		Salary (\$)	Bonus (\$)	Other Annual Compensation (\$)	Securities Under Option Granted (#)	
Dr. Brent Norton, President and Chief Executive Officer	Dec. 31, 2003	\$285,000	-	-	70,000	-
	Dec. 31, 2002	\$222,500	\$45,000	-	360,000	\$6,750
	Dec. 31, 2001	\$206,250	-	-	120,000	-
Michael Evelegh, Ph.D., Executive Vice President, Clinical and Regulatory Affairs	Dec. 31, 2003	\$225,000	-	-	50,000	-
	Dec. 31, 2002	\$215,000	\$105,000	-	110,000	-
	Dec. 31, 2001	\$183,334	-	-	60,000	-
Ronald Hosking, Vice President, Finance and Chief Financial Officer	Dec. 31, 2003	\$150,000	\$24,000	-	85,000	-
	Dec. 31, 2002	\$126,000	-	-	36,000	\$6,750
	Dec. 31, 2001	\$110,000	-	-	-	\$6,075

**Notes:**

- (1) In 2001, the Corporation changed its financial year end from January 31 to December 31. As a result the period ended December 31, 2001 is 11 months.
- (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, 2003**

No Long-term Incentive Plan Awards were made to the Named Executive Officers during the year ended December 31, 2003.



**3. Option Grants during the Year Ended December 31, 2003**

During the year ended December 31, 2003, 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
Dr. Brent Norton President and Chief Executive Officer	70,000	17.1%	\$4.00	\$4.00	Dec. 5, 2008
Michael Eveleigh, PhD Executive Vice President Clinical and Regulatory Affairs	50,000	12.2%	\$4.00	\$4.00	Dec. 5, 2008
Ronald Hosking, Vice President, Finance and Chief Financial Officer	50,000 35,000	12.2% 8.6%	\$2.85 \$4.00	\$2.85 \$4.00	Jun. 27, 2008 Dec. 5, 2008

**Note:** (1) These options will vest annually over periods from three to five years.

**4. Aggregated Option Exercises during the Year Ended December 31, 2003 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, 2003 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, 2003:

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>(3)</sup>
Dr. Brent Norton, President and Chief Executive Officer	-	-	625,000 <sup>(1)</sup> 407,500/217,500 <sup>(2)</sup>	\$452,250 \$371,250/\$81,000
Michael Eveleigh, PhD, Executive Vice President, Clinical and Regulatory Affairs	210,000	140,070	220,000 <sup>(1)</sup> 112,500/107,500 <sup>(2)</sup>	\$80,400 \$46,800/\$33,600

Ronald Hosking, Vice President, Finance and Chief Financial Officer	60,000	45,000	121,000 <sup>(1)</sup> 21,600/99,400 <sup>(2)</sup>	\$54,500 -/\$54,500
--	--------	--------	--	------------------------

---

**Notes:**

- (1) 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.
- (2) These options were not yet exercisable as the milestones or time periods referred to in note (1) above had not yet been attained.
- (3) Based upon a closing price of \$3.94 for the Common Shares on the Toronto Stock Exchange on December 31, 2003.

*Employee Share Purchase Plan*

The Corporation implemented a share purchase plan (the Purchase Plan) effective March 22, 1999, as amended, 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 of April 30, 2004, the Corporation has issued an aggregate of 93,522 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:

Name	Position	Term
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 - present
Anthony F. Griffiths	Director	July 13, 1995 - present
David A. Rosenkrantz	Director	June 11, 1998 - present

The Board of Directors was elected at the annual meeting of shareholders on June 18, 2003, and each director will serve until the next annual meeting of shareholders or until their resignation. During the year ended December 31, 2003, a total of \$61,500 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 (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.

The Corporation has entered into employment agreements with each of the Named Executive Officers. 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.

Dr. Brent Norton entered into an employment agreement with the Corporation on January 1, 2001. Pursuant to the terms of his employment agreement, Dr. Norton receives an annual base salary of two hundred and eighty five thousand dollars (\$285,000), which is reviewed annually and adjusted accordingly. This employment agreement also provides Dr. Norton with the right to receive options and bonuses at the discretion of the Board of Directors, as well as access to the benefit plans which IMI provides to its employees, including extended health, medical and dental insurance.

Dr. Michael Evelegh entered into an employment agreement with the Corporation on January 1, 2001. Pursuant to the terms of his employment agreement, Dr. Evelegh receives an annual base salary of two hundred and twenty five thousand dollars (\$225,000), which is reviewed annually and adjusted accordingly. This employment agreement also provides Dr. Evelegh with the right to receive options and bonuses at the discretion of the Board of Directors, as well as access to the benefit plans which IMI provides to its employees, including extended health, medical and dental insurance.

Unless terminated earlier pursuant to the terms of their respective agreements, Dr. Norton's and Dr. Evelegh's employment with the Corporation shall continue indefinitely. If either the employment of Dr. Norton or Dr. Evelegh is terminated by the Corporation without cause or, at the option of each of Dr. Norton or Dr. Evelegh, terminated in the event of a change of control (as such term is defined in their respective employment agreements) of the Corporation, then: (1) each is entitled to a cash payment equal to a percentage of their respective annual base salary as of that date; and (2) all of their options shall immediately vest and shall be exercisable or convertible for a period of 60 days after such termination. In addition, should Dr. Norton or Dr. Evelegh voluntarily resign or be terminated by the Corporation for cause or without cause, each of them is subject to a non-compete period of two years and one year, respectively.

Ron Hosking entered into an employment agreement with the Corporation on February 4, 1998. Pursuant to the terms of his employment agreement, Mr. Hosking receives an annual base salary of one hundred and fifty thousand dollars (\$150,000), which is reviewed annually and adjusted accordingly. This employment agreement also provides Mr. Hosking with the right to receive options and bonuses at the discretion of the Board of Directors, as well as access to the benefit plans which IMI provides to its employees, including extended health, medical and dental insurance.

Unless terminated earlier pursuant to his employment agreement, Ron Hosking's employment shall continue until January 12, 2003, at which time it may be renewed for successive one-year periods. Should Mr. Hosking's employment be terminated by the Corporation without cause, then: (1) he is entitled to a cash payment equal to a percentage of his annual base salary as of that date; and (2) all of his options 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.

The compensation committee of the Corporation's Board of Directors is made up of John C. Carroll, Anthony F. Griffiths, David A. Rosenkrantz and Stephen A. Wilgar, all of which are outside directors. 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.

The audit committee of the Corporation, composed entirely of outside directors, is 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. 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 17 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 which 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, 2004.

Name	Common Shares held directly and beneficially	% of Outstanding Common Shares as of April 30, 2003	Options outstanding	Exercise price	Expiration date
Dr. H.B. Brent Norton	2,519,268	11.7%	75,000	\$ 2.15	Sept. 13, 2004
			120,000	\$ 3.45	Feb. 1, 2006
			120,000	\$ 4.00	Feb. 16, 2007
			240,000	\$ 2.86	Nov. 16, 2007
Michael Eveleigh, Ph.D	650,561	3.0%	70,000	\$ 4.00	Dec. 5, 2008
			60,000	\$ 3.50	Feb. 1, 2006
			60,000	\$ 4.00	Feb. 16, 2007
			50,000	\$ 2.86	Nov. 16, 2007
Ronald G. Hosking	283,778	0.8%	70,000	\$ 4.00	Dec. 5, 2008
			36,000	\$ 4.00	Feb. 16, 2007
			50,000	\$ 2.85	Jun 27, 2008
Stephen A. Wilgar	270,808	1.3%	35,000	\$ 4.00	Dec. 5, 2008
			20,000	\$ 4.74	July 10, 2004
			20,000	\$ 4.61	July 17, 2005
			10,000	\$ 2.86	Nov. 16, 2007
John C. Carroll	263,442	1.2%	30,000	\$ 4.00	Dec. 5, 2008
			10,000	\$ 4.74	July 10, 2004
			10,000	\$ 4.61	July 17, 2005
			5,000	\$ 2.86	Nov. 16, 2007
Anthony F. Griffiths	510,500	2.4%	15,000	\$ 4.00	Dec. 5, 2008
			10,000	\$ 4.74	July 10, 2004
			10,000	\$ 4.61	July 17, 2005
			5,000	\$ 2.86	Nov. 16, 2007
			15,000	\$ 4.00	Dec. 5, 2008

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

David A. Rosenkrantz	392,733	1.8%	10,000	\$	3.80	July 10, 2004
			10,000	\$	4.61	July 17, 2005
			5,000	\$	2.86	Nov. 16, 2007
			15,000	\$	4.00	Dec. 5, 2008

*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 3,000,000 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:

Name	Number of Voting Securities Owned	
	Common Shares	Percentage of Class
Dr. H.B. Brent Norton	2,519,268	11.7%

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

As of April 30, 2004, 66 of the record holders of the Common Shares are citizens or residents of the U.S., or corporations created or organized in or under the laws of the U.S., representing ownership of approximately 12% of the total outstanding Common Shares.

**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 April 30, 2004 are as follows:

Name	Date	Principal (\$)	Interest (\$)	Total Outstanding as of April 30, 2004(\$)
Ronald G. Hosking	Nov-1998	10,005	64	10,169
Michael Eveleigh, Ph.D.	Mar-2002	120,000	2,489	122,489
<hr/>				
Total		130,005	2,553	132,558

**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:

- 1 Consolidated Balance Sheets
- 1 Consolidated Statements of Loss and Deficit
- 1 Consolidated Statements of Cash Flows
- 1 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**

On May 28, 2004 the Corporation expanded its relationship with McNeil and signed an exclusive worldwide licensing agreement for the Corporation's skin cholesterol-based cardiac risk prediction tests. These products will be marketed by McNeil and its worldwide affiliates under the brand name PREVU\* Coronary Heart Disease Predictor. This agreement has a minimum term of 10 years. Under the financial terms of the



agreement, the Corporation receives a \$3.0 million up front payment as well as a series of milestone payments of up to \$15.75 million in addition to sales and royalties. Since future royalty rates,

royalties and milestone payments under this agreement are based on specific sales targets, the Corporation is unable at this time to accurately predict the aggregate future payments that could be received under this agreement.

**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-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	-	-
Jan-00	3.10	0.60	-	-

(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 (\$)
Q1/04 Jan-Mar	4.25	\$3.60	\$3.30	2.70
Q4/03 Oct-Dec	4.70	3.60	3.60	2.84
Q3/03 July-Sept	4.89	2.67	3.65	2.88
Q2/03 Apr-Jun	3.00	2.41	-	-
Q1/03 Jan-Mar	3.25	2.50	-	-
Q4/02 Oct-Dec	3.85	2.20	-	-
Q3/02 July-Sept	5.80	3.50	-	-
Q2/02 Apr-Jun	7.15	4.75	-	-
Q1/02 Jan-Mar	6.10	3.65	-	-

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

	TSX		AMEX	
	High (\$)	Low (\$)	High (\$)	Low (\$)
May-04	4.70	2.60	3.40	1.88
Apr-04	3.74	3.25	3.07	2.47
Mar-04	4.10	3.60	3.05	2.70
Feb-04	4.05	3.71	3.06	2.80
Jan-04	4.25	3.71	3.30	2.90
Dec-03	4.21	3.63	3.20	2.84
Nov-03	4.35	3.60	3.40	2.90

(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.

*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:

- 1 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;
- 1 hold Common Shares as capital assets for purposes of the Code and capital property for the purposes of the Income Tax Act;
- 1 deal at arm's length with, and are not affiliated with, the Corporation for purposes of the Income Tax Act; and
- 1 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:

- 1 the Income Tax Act and regulations under the Income Tax Act;
- 1 the Code and Treasury regulations under the Code;
- 1 the Canada-United States Income Tax Convention (1980);
- 1 the administrative policies and practices published by the Canada Customs and Revenue Agency, formerly Revenue Canada;
- 1 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;
- 1 the administrative policies published by the U.S. Internal Revenue Service; and
- 1 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.

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 31% 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.

#### *Foreign Personal Holding Company Rules*

Special U.S. tax rules apply to a shareholder of a foreign personal holding company ( FPHC ). The Corporation would be classified as a FPHC in any taxable year if both of the following tests are satisfied:

- 1 five or fewer individuals who are U.S. citizens or residents own or are deemed to own more than 50% of the total voting power of all classes of the Corporation's stock entitled to vote or the total value of the Corporation's stock; and
- 1 at least 60% of the Corporation's gross income consists of foreign personal holding company income, which generally includes passive income such as dividends, interest, gains from the sale or exchange of stock or securities, rents and royalties.

The Corporation believes that they are not a FPHC. However, the Corporation cannot assure you that the Corporation will not be classified as a FPHC in the future.

#### *Personal Holding Company Rules*

The Corporation will not be classified as a personal holding company (a PHC ) for U.S. federal income tax purposes unless any time during the last half of the Corporation's taxable year, five or fewer individuals (without regard to their citizenship or residency) own or are deemed to own (pursuant to certain attribution rules) more than 50% of the Corporation's stock by value, and at least 60% of the Corporation's ordinary gross income for the taxable year is personal holding company (generally passive income such as dividends and interest). The Corporation should not meet the PHC tests, and even if the Corporation were to become a PHC, it does not expect to have material undistributed PHC income. However, the Corporation cannot assure you that it will not become a PHC because of uncertainties regarding the application of the constructive ownership rules and the possibility of changes in its shareholder base and income or other circumstances that could change the application of the PHC rules to the Corporation. In addition, if the Corporation should become a PHC, the Corporation cannot assure you that the amount of its PHC income will be immaterial.

#### *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:

- 1 75% or more of the Corporation's gross income is passive income, which includes interest, dividends and certain rents and royalties; or
- 1 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 and it does not expect to become a PFIC in future years. Whether the Corporation is a PFIC in any year, the tax consequences relating to PFIC status will depend on the composition of the Corporation's income and assets, including cash. 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's 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.

Dividends paid, credited or deemed to have been paid or credited on the Common Shares to Unconnected U.S. Shareholders will be subject to a Canadian withholding tax under the Income Tax Act at a rate of 25% of the gross amount of the dividends. Under the Canada-United States Income Tax Convention (1980), the rate of withholding tax on dividends generally applicable to Unconnected U.S. Shareholders who beneficially own the dividends is reduced to 15%. In the case of Unconnected U.S. Shareholders that are corporations that beneficially own at least 10% of the Corporation's voting shares, the rate of withholding tax on dividends generally is reduced to 5%. United States limited liability companies (LLCs) will not be entitled to these reduced rates. Shareholders that are partnerships will be subject to the 25% rate.

Canada does not currently impose any federal estate taxes or succession duties. However, if you die, there is a deemed disposition of the Common Shares held at that time for proceeds of disposition generally equal to the fair market value of the Common Shares immediately before your death. Capital gains realized on the deemed disposition, if any, will have the income tax consequences described above.

***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 450 Fifth Street, N.W., Room 1024, 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 which 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]**

**A. *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 Patica 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

**B. Code of Ethics/Code of Business Conduct**

The Corporation adopted a Code of Business Conduct and has filed it as an Exhibit to this Form 20-F

**C. 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 2002 and 2003.

	2002		2003	
	Amount	%	Amount	%
Audit Fees	\$ 124,270	89.6	112,433	91.6
Audit-Related Fees	-	-	-	-
Tax Fees <sup>(1)</sup>	14,499	10.4	10,280	8.4
All Other Fees	-	-	-	-
<b>Total</b>	<b>138,769</b>	<b>100.0</b>	<b>122,713</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 our board of directors chooses and engages our independent auditors to audit our financial statements. In 2003, our audit committee also adopted a policy requiring management to obtain the audit committee's approval before engaging our independent auditors to provide any other audit or permitted non-audit services to us or our subsidiaries. This policy, which is designed to assure that such engagements do not impair the independence of our auditors, requires the audit committee to pre-approve audit and non-audit services that may be performed by our auditors.

On a quarterly basis, we inform the audit committee of the pre-approved services actually provided by our 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 our audit committee is not permitted to approve any engagement of our 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.

**D. Exemptions from the Listing Standards for Audit Committee**

Not applicable.

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

Not applicable.



**PART III**

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

Not Applicable.

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

**REPORT OF INDEPENDENT AUDITORS**

To the Shareholders of  
**IMI International Medical Innovations Inc.**

We have audited the consolidated balance sheets of **IMI International Medical Innovations Inc.** as at December 31, 2003 and 2002 and the consolidated statements of loss and deficit and cash flows for the years ended December 31, 2003 and 2002 and the 11-month period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with Canadian and United States generally accepted auditing standards. Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation.

In our opinion, these consolidated financial statements present fairly, in all material respects, the financial position of the Company as at December 31, 2003 and 2002 and the results of its operations and its cash flows for the years ended December 31, 2003 and 2002 and the 11-month period ended December 31, 2001 in accordance with Canadian generally accepted accounting principles.

As described in note 2 to the consolidated financial statements, the Company changed its method of accounting for stock-based compensation in 2003.

Toronto, Canada,  
March 5, 2004

/s/ Ernst & Young LLP  
Chartered Accountants

**IMI International Medical Innovations Inc.**

Incorporated under the laws of Canada

**CONSOLIDATED BALANCE SHEETS**

As at December 31

	2003	2002
	\$	\$
<b>ASSETS</b>		
<b>Current</b>		
Cash and cash equivalents	61,625	150,451
Short-term investments	6,635,135	9,961,743
Prepaid expenses and other receivables	340,489	237,591
Investment tax credits receivable	180,000	271,000
<b>Total current assets</b>	<b>7,217,249</b>	<b>10,620,785</b>
Capital assets, net <i>[note 3]</i>	403,205	191,632
Acquired technology, net of accumulated amortization of \$693,684 [2002 - \$580,291] <i>[note 4[d][ii]]</i>		453,573
		566,966
		<b>8,074,027</b>
		11,379,383

**LIABILITIES AND SHAREHOLDERS' EQUITY****Current**



Accounts payable

**139,435**

180,303

Accrued liabilities

**403,213**

409,252

---

**Total current liabilities**

**542,648**

589,555

---

Deferred revenue *[note 6[a]]*

**93,100**

100,000

---

**Total liabilities**

**635,748**

689,555

---

Commitments *[note 6]*

**Shareholders' equity**

Capital stock *[note 4]*

**24,780,846**

23,785,884

Warrants *[notes 4[d] and 6[b][iv]]*

**312,200**

496,000

Deficit

**(17,654,767)**

)

(13,592,056

)

**Total shareholders' equity**

**7,438,279**

10,689,828

**8,074,027**

11,379,383

*See accompanying notes*

On behalf of the Board:

Director

Director

## IMI International Medical Innovations Inc.

## CONSOLIDATED STATEMENTS OF LOSS AND DEFICIT

	Year ended December 31, 2003 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
<b>EXPENSES</b>			
Research and development	1,918,800	2,104,904	2,047,116
General and administration	2,361,602	2,141,207	1,500,434
Amortization	280,777	219,466	215,236
	<b>4,561,179</b>	<b>4,465,577</b>	<b>3,762,786</b>
<b>RECOVERIES AND OTHER INCOME</b>			
Investment tax credits	223,146	189,908	131,000
Interest	275,322	257,407	386,580
	<b>498,468</b>	<b>447,315</b>	<b>517,580</b>
<b>Net loss for the period</b>	<b>(4,062,711)</b>	<b>(4,018,262)</b>	<b>(3,245,206)</b>
Deficit, beginning of period	<b>(13,592,056)</b>	<b>(9,573,794)</b>	<b>(6,328,588)</b>
<b>Deficit, end of period</b>	<b>(17,654,767)</b>	<b>(13,592,056)</b>	<b>(9,573,794)</b>
<b>Basic and diluted loss per share</b>	<b>\$ (0.19)</b>	<b>\$ (0.20)</b>	<b>\$ (0.17)</b>

Weighted average number of common shares  
outstanding

20,967,677

20,406,733

19,097,390

*See accompanying notes*

64

---

## IMI International Medical Innovations Inc.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31, 2003 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
<b>OPERATING ACTIVITIES</b>			
Net loss for the period	(4,062,711)	(4,018,262)	(3,245,206)
Add items not involving cash			
Amortization	280,777	219,466	215,236
Stock compensation costs included in:			
Research and development expense	189,105	81,905	
General and administration expense	255,112	36,483	
Loss on sale of capital asset	3,873		1,139
	(3,333,844)	(3,680,408)	(3,028,831)
Net change in non-cash working capital balances related to operations <i>[note 7]</i>			(61,870)
)			130,841
)			(209,865)
<b>Cash used in operating activities</b>			<b>(3,395,714)</b>
)			(3,549,567)
)			(3,238,696)
<b>INVESTING ACTIVITIES</b>			

Short-term investments	<b>3,326,608</b>
)	(2,603,943
	642,836
Purchase of acquired technology <i>[note 4[d][ii]]</i>	
)	(381,507
Purchase of capital assets	
)	<b>(385,605</b>
)	(20,804
)	(275,492
Proceeds on sale of capital asset	
	<b>2,775</b>
	2,376
<hr/>	
<b>Cash provided by (used in) investing activities</b>	<b>2,943,778</b>
)	(2,624,747
)	(11,787
<hr/>	

**FINANCING ACTIVITIES**

Issuance of capital stock, net of issue costs	<b>363,110</b>
	5,731,386
	1,278,328
<hr/>	
<b>Cash provided by financing activities</b>	<b>363,110</b>
	5,731,386
	1,278,328
<hr/>	
<b>Net decrease in cash and cash equivalents during the period</b>	
)	<b>(88,826)</b>
)	(442,928)
)	(1,972,155)
Cash and cash equivalents, beginning of period	<b>150,451</b>
	593,379
	2,565,534
<hr/>	
<b>Cash and cash equivalents, end of period</b>	<b>61,625</b>
	150,451
	593,379
<hr/>	

Represented by:

Cash			<b>61,625</b>
			148,270
			376,190
Cash equivalents			
			2,181
			217,189
<hr/>			
			<b>61,625</b>
			150,451
			593,379

*See accompanying notes*



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

[In Canadian dollars, unless otherwise noted]

### 1. NATURE OF THE COMPANY AND BASIS OF PRESENTATION

IMI International Medical Innovations Inc. [the "Company"] operates in a single business segment and is a predictive medicine company dedicated to developing rapid, non-invasive tests for the early detection of life-threatening diseases, particularly cardiovascular disease and cancer. The Company licenses, develops and initiates the commercialization of novel, medical technologies developed by various research institutions throughout the world.

The Company currently owns patents for a test used to measure skin cholesterol and has in-licensed the technologies for tests to detect the presence of a cancer-specific marker for use in colorectal, lung and other cancers. In addition, the Company has patents pending for color measurement in biological reactions and has a right of first refusal on certain genomics-related technologies in the predictive medicine field.

In December 2001, the Company changed its fiscal year end from January 31 to December 31, therefore comparative consolidated statements of loss and deficit and cash flows are presented for the 11-month period ended December 31, 2001.

### 2. SIGNIFICANT ACCOUNTING POLICIES

#### New Pronouncements

Effective January 1, 2003, the Company adopted the guidelines relating to the disclosure by a guarantor in its financial statements about obligations under certain types of guarantees that it has issued as required by The Canadian Institute of Chartered Accountants' ["CICA"] Accounting Guideline No. 14, "Disclosure of Guarantees". The adoption of this pronouncement had no effect on the Company's consolidated financial statements.

Effective January 1, 2004, the Company will adopt CICA Handbook Section 3063, "Impairment of Long-Lived Assets" that was issued during 2003. Adopting this section will impact the recognition, measurement and disclosure of the impairment of long-lived assets on a prospective basis. A loss is recognized on a long-lived asset held for use when its carrying value exceeds the undiscounted cash flows from its use and disposition. The amount of the loss is determined by deducting the asset's fair value [based on discounted cash flows] from its carrying value. Previously, the loss was determined by deducting the asset's net recoverable value [based on undiscounted cash flows] from its carrying value. The Company has reviewed its policies and determined that there is no impact as a result of the Company adopting this section.

During 2003, the CICA issued Accounting Guideline No. 15, "Consolidation of Variable Interest Entities" ["AcG-15"]. AcG-15 sets out the criteria for identifying variable interest entities and criteria for determining what entity, if any, should consolidate them. The company will adopt the disclosure requirements of AcG-15 effective January 1, 2004 and is currently reviewing the impact of the Guideline.

The consolidated financial statements have been prepared by management in accordance with Canadian generally accepted accounting principles ["Canadian GAAP"] consistently applied within the framework of the significant accounting policies summarized below. With respect to the consolidated financial statements of the Company, the significant differences between Canadian and United States generally accepted accounting principles ["U.S. GAAP"] are described and reconciled in note 8.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

**Basis of consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary, IMI International Medical Innovations Inc. Berne, incorporated under the laws of Switzerland. All significant intercompany transactions and balances have been eliminated upon consolidation.

**Revenue recognition**

License revenue is recognized over the term of the related license.

**Foreign currency translation**

Foreign operations are considered integrated and are translated using the temporal method. Monetary items are translated using the exchange rate in effect at the period end and non-monetary items are translated at historical exchange rates. Revenue and expenses are translated at the average rate for the period except for amortization of capital assets, which is translated at the same exchange rates as the assets to which they relate. Exchange gains or losses are included in the determination of net loss for the period.

**Cash and cash equivalents**

Cash and cash equivalents comprise cash on hand and highly liquid investments that are readily convertible into cash with maturities of less than 90 days when purchased. Cash equivalents at December 31, 2003 were comprised of money market funds with an average interest rate of 2.6% [2002 - 2.6%].

**Short-term investments**

Short-term investments are carried at the lower of cost and market. Short-term investments at December 31, 2003 were comprised of bonds and bankers' acceptances with interest rates of approximately 2.6% [2002 - 2.8%]. Short-term investments are comprised of highly liquid investments with maturity periods greater than 90 days but less than one year when purchased.

**Capital assets**

Capital assets are recorded at acquisition cost less accumulated amortization.

The Company provides for amortization on the declining balance basis at rates which are expected to charge operations with the cost of the assets over their estimated useful lives as follows:

Computer equipment	30%
Furniture and equipment	20%
Research instrumentation	30%
Laboratory equipment	20%
Leasehold improvements	straight-line over the term of the lease

**Acquired technology**

Patents and technology acquired by the Company are recorded at acquisition cost and are amortized on a declining balance basis at 20% per year. The Company records a write-down in acquired technology when there is a change in circumstances, such as unfavourable clinical trial results, suggesting an impairment has occurred.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

[In Canadian dollars, unless otherwise noted]

### Guarantees

Many of the Company's agreements, specifically those related to financing, research and development and supply arrangements, include indemnification provisions where the Company may be required to make payment to the counterparty. Such payments relate to personal injury resulting from clinical trials and from breach of fundamental representation and warranty terms in the agreements with respect to matters such as corporate status, title of assets, consents to transfer, employment matters, litigation and other potential material liabilities. The maximum potential amount of future payments that the Company could be required to make under these indemnification provisions is not reasonably quantifiable as certain indemnifications are not subject to a monetary limitation. At December 31, 2003, management believes there is only a remote possibility that the indemnification provisions would require any material cash payment.

The Company indemnifies its directors and officers against any and all claims or losses reasonably incurred in the performance of their service to the Company to the extent permitted by law. The Company has acquired and maintains liability insurance for its directors and officers.

### Financial instruments

The carrying values of cash and cash equivalents, short-term investments, other receivables and accounts payable and accrued liabilities are considered to approximate their respective fair values due to their short term nature.

### Research and development and related investment tax credits

Research and development expenditures include related salaries, subcontractor fees, product development expenses including patent costs, clinical trials costs and an allocation of administrative expenses and corporate costs specifically attributable to research and development. Research and development excludes any costs associated with the acquisition of capital assets and acquired technology. Research and development expenditures are charged to expenses as incurred unless management believes a development cost meets the generally accepted criteria for deferral. All development costs incurred to date have been expensed. Advance collaboration funding, which is a reimbursement for specific expenditures, has been applied against research and development.

Investment tax credits earned as a result of incurring qualified scientific research and experimental development expenses are recorded when the amounts are readily determinable. The amounts are recorded as follows:

1 for capital assets - as a reduction of the cost of the related asset; and

1 for operating expenses - as a recovery within the consolidated statements of loss and deficit.

### Income taxes

The Company applies the asset and liability method of accounting for income taxes. Under this method, future income tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using substantively enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. Valuation allowances are provided if it is more likely than not that some or all of the future tax assets will not be realized.

### Loss per share

Loss per share has been calculated on the basis of net loss for the period divided by the weighted average number of common shares outstanding during the period. Diluted loss per share reflects the dilution that would occur if outstanding stock options and warrants were exercised or converted into common shares using the treasury stock

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

method. The inclusion of the Company's stock options and warrants in the computation of diluted loss per share would have an anti-dilutive effect on loss per share. Therefore, stock options and warrants have been excluded from the calculation of diluted loss per share. Consequently, there is no difference between basic loss per share and diluted loss per share.

**Use of estimates**

The preparation of consolidated financial statements in conformity with Canadian GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ materially from those estimates.

**Stock-based compensation**

The Company has two stock-based compensation plans, which are described in notes 4[e] and [f].

Effective January 1, 2002, stock options and other equity instruments issued to non-employees and direct awards of stock granted to employees are accounted for using the fair value method of accounting. Prior to January 1, 2002, there was no recognition of stock options and equity instruments issued to non-employees as it was not prescribed by Canadian GAAP.

On January 1, 2003, the Company prospectively adopted the recommendations in CICA Handbook Section 3870, "Stock-Based Compensation and Other Stock-Based Payments" ["Section 3870"]. The new recommendations are generally applicable only to awards granted after the date of adoption.

Section 3870 requires that options issued to employees are accounted for using the fair value method of accounting. Previously, no compensation expense was recognized for stock options granted to employees.

For stock options awarded to employees prior to January 1, 2003 but subsequent to January 1, 2002, pro forma disclosure of net loss and loss per share is provided as if these awards were accounted for using the fair value method.

Consideration paid on the exercise of stock options and warrants is credited to capital stock.

The table below presents pro forma net loss and basic and diluted loss per common share as if stock options granted to employees between January 1, 2002 and December 31, 2002 had been determined based on the fair value method.

Effective January 1, 2002, shares issued to employees under the share purchase plan are accounted for as direct awards of stock and are recognized as an expense in the consolidated statements of loss and deficit [note 4[f]]. Shares issued to employees on the exercise of options in exchange for non-recourse loans are accounted for as options.

	<b>2003</b>		<b>2002</b>
	\$		\$
Net loss as reported	<b>(4,062,711)</b>		(4,018,262)
Estimated stock-based compensation costs	<b>(250,350)</b>		(713,589)
<b>Pro forma net loss</b>	<b>(4,313,061)</b>		(4,731,851)
<b>Pro forma basic and diluted loss per common share</b>	<b>\$ (0.21)</b>	<b>\$</b>	<b>(0.23)</b>



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

The assumptions used to calculate the estimated stock-based compensation costs are consistent with those used for U.S. GAAP reporting purposes [note 8[g]].

**3. CAPITAL ASSETS**

Capital assets consist of the following:

	2003		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Computer equipment	192,671	111,659	81,012
Furniture and equipment	55,802	38,936	16,866
Research instrumentation	568,753	282,587	286,166
Laboratory equipment	25,456	9,197	16,259
Leasehold improvements	8,705	5,803	2,902
	<b>851,387</b>	<b>448,182</b>	<b>403,205</b>

	2002		
	Cost	Accumulated amortization	Net book value
	\$	\$	\$
Computer equipment	126,402	87,037	39,365
Furniture and equipment	55,802	34,719	21,083
Research instrumentation	284,312	159,944	124,368
Laboratory equipment	7,306	5,133	2,173
Leasehold improvements	8,705	4,062	4,643
	<b>482,527</b>	<b>290,895</b>	<b>191,632</b>

**4. CAPITAL STOCK**

**[a] Authorized**

The authorized capital stock of the Company consists of an unlimited number of common shares, without nominal or par value, and an unlimited number of preferred shares, issuable in series.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

**[b] Issued and outstanding shares**

Common shares	Number #	Stated value \$	Contributed surplus	Total
	\$			
	\$			
<hr/>				
<b>Balance, January 31, 2001</b>				18,655,199
				16,863,108
			71,054	
				16,934,162
Issued on exercise of warrants <i>[note 4[d]]</i>				753,358
				1,147,611
				1,147,611
Issued under share purchase plan <i>[note 4[f]]</i>				12,087
Issued on exercise of options <i>[note 4[e]]</i>				



	144,750
	130,717
	130,717
<hr/>	
<b>Balance, December 31, 2001</b>	
	19,565,394
	18,141,436
	71,054
	18,212,490
Issued on exercise of warrants	
	4,202
	25,000
	25,000
Expiry of warrants	
	5,000
	5,000
<i>Issued pursuant to private placement [note 4[c]]</i>	
	1,200,000
	5,282,196
	5,282,196
Issuance of stock options <i>[note 4[e]]</i>	

	43,234
	43,234
Issued under share purchase plan <i>[note 4[f]]</i>	
	9,764
	47,219
	47,219
Issued on exercise of options <i>[note 4[e]]</i>	
	377,600
	425,790
	425,790
Share purchase loans <i>[note 4[e]]</i>	
)	(375,000)
)	(255,045)
)	(255,045)
<hr/>	
<b>Balance, December 31, 2002</b>	
	20,781,960
	23,666,596
	119,288
	23,785,884
Expiry of warrants	
	191,000

	191,000
Issuance of stock options <i>[note 4[e]]</i>	
	413,705
	413,705
Issued under share purchase plan <i>[note 4[f]]</i>	
	8,942
	27,147
	27,147
Issued on exercise of options <i>[note 4[e]]</i>	
	290,000
	238,070
	238,070
Repayment of share purchase loans <i>[note 4[e]]</i>	
	180,000
	125,040
	125,040
<hr/>	
<b>Balance, December 31, 2003</b>	
	<b>21,260,902</b>
	<b>24,056,853</b>
	<b>723,993</b>
	<b>24,780,846</b>
<hr/>	

**[c] Private placement**

**Year ended December 31, 2002 transactions**

During the year ended December 31, 2002, the Company issued by way of private placement, 1,200,000 common shares at a price of \$5.00 per common share for gross proceeds of \$6,000,000 less issue costs of \$529,404 [net \$5,470,596].

In connection with this offering, the Company granted to the agent compensation warrants to purchase up to 120,000 common shares at an exercise price of \$5.50 per share, exercisable at any time on or before April 2, 2003. The fair value of the warrants at the date of grant was estimated as \$188,400, using the Black-Scholes option pricing model. The assumptions used to calculate the fair value of the warrants are as follows: expected volatility of 49%, risk-free interest rate of 3.42%, and expected warrant life of one year. The warrants expired unexercised on April 2, 2003.

**[d] Warrants**

**[i] Year ended December 31, 2003 transactions**

During the year ended December 31, 2003, the Company issued 10,000 warrants, pursuant to a research collaboration agreement dated October 31, 2000, at an estimated fair value of \$7,200. Under the terms of the agreement, the Company granted warrants to purchase up to 50,000 common shares at an exercise price of \$4.50, such warrants to be issued in annual increments of 10,000 warrants exercisable immediately and

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

[In Canadian dollars, unless otherwise noted]

expiring in one year. During each of the year ended December 31, 2002 and the 11-month period ended December 31, 2001, the Company issued 10,000 of these warrants, which expired unexercised on October 31, 2003 and October 31, 2002, respectively.

For valuation purposes, the Company has applied the Black-Scholes option pricing model to determine the estimated fair value of the warrants. The assumptions used to calculate the fair value of the warrants are as follows: expected volatility of 42%, risk-free interest rate of 3.06%, and expected warrant life of one year.

The Company provided loans to two of its executive officers during the year ended December 31, 2002, totaling \$165,000, one executive officer during the 11-month period ended December 31, 2001 [\$60,030] and two executive officers during the year ended January 31, 1999 [\$30,015] in order to exercise options and warrants. The balance of these loans at December 31, 2003 was \$130,005 [2002 - \$255,045]. The loans outstanding as at year end bear interest at 5%, are payable on demand and are unsecured. Repayments of \$125,040 were received by the Company during the year, and have been reflected as issuance of capital stock within the statement of cash flows. The amount of all loans outstanding has been deducted from capital stock until such time as the loans are repaid.

### **[ii] 11-month period ended December 31, 2001 transactions**

During the 11-month period ended December 31, 2001, pursuant to a license agreement, the Company granted warrants to purchase up to 75,000 common shares at an exercise price of \$4.50 which have an estimated fair value of \$108,000. The warrants are exercisable as follows: [i] 37,500 common shares at any time after March 2002 and prior to March 2004, and [ii] 37,500 common shares at any time after March 2003 and prior to March 2004. Pursuant to another license agreement, the Company granted warrants to purchase up to 100,000 common shares at exercise prices ranging from \$3.50 to \$4.50, which have an estimated fair value of \$197,000 and expire in 2006. The fair values have been estimated using the Black-Scholes option pricing model.

The technologies acquired through these license agreements relate to the ColorectAlert License Agreement and to the Procyon License Agreement [note 6[b][iii]]. Total consideration paid for these technologies was \$686,507, of which \$381,507 was paid in cash and the balance in warrants, with an estimated fair value of \$305,000.

During the 11-month period ended December 31, 2001, 753,358 common shares were issued for total proceeds of \$1,147,611 in connection with options granted during the years ended January 31, 2001 and 2000 to the agent of the Company's private placements and holders of the purchase warrants.

### **[e] Options**

Prior to May 1, 1998, the Company granted options to its employees, directors and consultants under a stock option plan, of which none of these options remain outstanding as at December 31, 2003. Under the new 1998 Stock Option Plan, the Company may issue options for up to 3,000,000 common shares. As at December 31, 2003, 2,174,135 options had been issued, of which 1,971,785 remain outstanding, under this plan and the remaining 825,865 are eligible to be issued. The exercise price of each option granted may not be less than the market price of the Company's stock at the time of the grant and no option may have a term exceeding 10 years.

Certain of the options vest over a fixed term and others vest based on performance upon the achievement of certain milestones. A summary of the status of the two types of options are presented below:

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

**Fixed stock options**

Fixed stock options vest on an annual basis over a period of up to five years. A summary of the status of fixed stock options as at December 31, 2003, 2002 and 2001 and changes during the years and 11-month period ended on those dates is presented below:

	December 31, 2003		December 31, 2002		December 31, 2001	
	Number of shares #	Weighted average exercise price \$	Number of shares #	Weighted average exercise price \$	Number of shares #	Weighted average exercise price \$
<b>Outstanding, beginning of period</b>					1,310,750	3.44
					981,750	2.43
					829,000	1.70
<b>Granted</b>					559,285	3.43
					714,000	3.59
					308,750	3.71
<b>Exercised</b>					(20,000)	2.65
)						
						102

)	(377,600)
	1.13
)	(144,750)
	0.90
Expired or forfeited	
)	<b>(93,000)</b>
	<b>3.32</b>
)	(7,400)
	2.02
)	(11,250)
	3.65
<hr/>	
<b>Outstanding, end of period</b>	
	<b>1,757,035</b>
	<b>3.45</b>
	1,310,750
	3.44
	981,750
	2.43
<hr/>	
<b>Options exercisable at period end</b>	
	<b>973,700</b>
	764,350
	829,400
	103

The following table summarizes information about stock options outstanding at December 31, 2003:

Range of exercise prices \$	Number outstanding #	Weighted average remaining life [in years]	Weighted average exercise price \$	Number exercisable #	Weighted average exercise price \$
2.15 - 2.99	755,285	3.43	2.74	376,000	2.66
3.00 - 3.65	248,250	2.16	3.46	212,400	3.47
4.00 - 4.74	733,500	3.47	4.10	381,300	4.19
6.05 - 6.05	20,000	3.43	6.05	4,000	6.05
	<b>1,757,035</b>			<b>973,700</b>	

#### Performance stock options

Performance stock options vest immediately upon the achievement of certain milestones as determined by the Board of Directors at the time of issuance. Compensation expense for performance stock options is recorded when it is determined that achievement of the milestone is likely. The performance stock option milestones include criteria measured by product-related goals and corporate goals. Product-related goals include: product development, completion of clinical trials, regulatory submissions, regulatory approvals, signing of marketing partners and commercial launch of the Company's products. The corporate goals include: successful investor and public relations activities related to media publications and investor analyst coverage, as well as financial goals including completion of financings and government grants.



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

A summary of the status of performance stock options as at December 31, 2003, 2002 and 2001 and changes during the years and 11-month period ended on those dates is presented below:

	December 31, 2003		December 31, 2002		December 31, 2001	
	Number of shares #	Weighted average exercise price \$	Number of shares #	Weighted average exercise price \$	Number of shares	Weighted average exercise price
<b>Outstanding, beginning of period</b>					487,750	1.96
					615,250	1.26
					560,000	0.99
<b>Granted</b>						
					85,500	3.91
					70,250	3.74
<b>Exercised</b>						
					105	

)	(270,000)
	0.69
Expired or forfeited	
)	(3,000)
	3.55
)	(213,000)
	0.72
)	(15,000)
	3.65
<hr/>	
<b>Outstanding, end of period</b>	
	<b>214,750</b>
	<b>3.54</b>
	487,750
	1.96
	615,250
	1.26
<hr/>	
<b>Options exercisable at period end</b>	
	<b>111,275</b>
	368,075
	106

The following table summarizes information about stock options outstanding at December 31, 2003:

Range of exercise prices \$	Number outstanding #	Weighted average remaining life [in years]	Weighted average exercise price \$	Number exercisable #	Weighted average exercise price \$
2.50 - 3.45	79,750	2.27	2.69	45,975	2.65
4.00 - 4.30	135,000	2.77	4.04	65,300	4.07
	214,750			111,275	

**[f] Employee share purchase plan**

As a result of ongoing interest by its employees and directors to purchase shares of the Company, the Company implemented a share purchase plan effective March 22, 1999, as amended. Pursuant to the terms of the plan, the Company will match the value of the common shares purchased by its employees or directors by issuing from treasury an equal number of common shares, up to a maximum value of the lesser of 50% of the maximum allowable annual contribution for registered retirement savings plans (being \$7,250 as at December 31, 2003) or 9% of the employee's annual salary. The maximum number of common shares which may be issued by the Company pursuant to the share purchase plan is 350,000. Under the plan, the Company issued 8,942 common shares to employees and directors during the year ended December 31, 2003 and 9,764 and 12,087 shares during the year ended December 31, 2002 and the 11-month period ended December 31, 2001, respectively.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

**5. INCOME TAXES**

[a] Significant components of the Company's future tax assets and liabilities are as follows:

	2003	2002
	\$	\$
<b>Future tax assets</b>		
Federal tax loss carryforwards	1,902,320	1,531,630
Ontario tax loss carryforwards	1,343,618	633,732
Financing and share issue costs	203,430	242,264
SR&ED expenditures	2,169,052	1,365,816
Capital assets	41,876	9,674
Future tax assets before valuation allowance	5,660,296	3,783,116
Valuation allowance	(5,660,296)	(3,783,116)
<b>Net future tax assets (liabilities)</b>		

No net future tax assets have been recognized in the consolidated financial statements as the realization of the net future tax assets does not meet the more likely than not recognition criteria.

[b] The Company has accumulated tax losses for federal and provincial purposes in Canada. The Company also has unclaimed federal Canadian scientific research investment tax credits. The losses and investment tax credits can be used to offset future years' Canadian taxable income, the benefit of which has not been recorded in the accounts. The approximate tax losses and investment tax credits expire as follows:

	Federal	Ontario	Investment tax credits
	\$	\$	\$
2004		147,000	
2005	351,000	767,000	
2006	832,000	989,000	
2007	1,062,000	1,340,000	
2008	1,562,000	1,562,000	
2009	2,731,000	2,731,000	
2010	2,061,000	2,061,000	
2011			
2012			898,625
2013			396,292
	8,599,000	9,597,000	1,294,917

- [c] The Company has available scientific research and experimental development (SR&ED) expenditures for income tax purposes which may be carried forward indefinitely to reduce future years' taxable income. The total of such expenditures accumulated to December 31, 2003 is approximately \$6,005,000. The potential income tax benefits associated with these expenditures have not been recorded in the accounts.
- [d] The Company is entitled to receive Provincial investment tax credits relating to relating to scientific research and experimental development costs incurred, the benefits of which have been accrued in the accounts.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2003

[In Canadian dollars, unless otherwise noted]

### 6. COMMITMENTS

#### [a] Commercialization agreement

- [i] On May 10, 2002 the Company entered into an agreement with McNeil Consumer Healthcare ["McNeil"] to market and distribute the Company's test for coronary artery disease in Canada. Pursuant to an amendment to this agreement, dated December 20, 2002, and upon payment to the Company of \$100,000, McNeil exercised an option to expand its marketing rights in Canada to include the laboratory field and to extend the territory for the insurance testing market to include the United States and Mexico. The amended agreement provides McNeil with exclusive rights, in these fields and in this territory, to the professional skin cholesterol test system and all future versions which will be jointly developed by McNeil and the Company. The term of the agreement is 15 years and requires McNeil to purchase the Company's skin cholesterol test and to pay ongoing royalties to the Company 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 Company may terminate this agreement if certain minimum levels of sales are not met. Since all future royalties and milestone payments under this agreement are based on sales by McNeil, which sales have not commenced, the Company is unable at this time to estimate the aggregate future payments that could be received under this agreement.

#### [b] Research and collaboration agreements

The Company has entered into agreements with various clinical sites to conduct clinical trials on its technologies. The Company is committed upon the progressive completion of the trials to make further payments of approximately \$982,000.

The Company has acquired or is developing in collaboration with others a number of technologies which will require the Company to make payments upon the successful achievement of certain technological milestones. Additionally, in connection with the development of the technologies, the Company has entered into research agreements whereby a minimum fee will be paid for research and development to be carried out by other parties. The Company is committed, upon the successful achievement of future operating performance milestones, to make further payments of approximately \$609,000 and to issue up to 10,000 purchase warrants at an exercise price of \$4.50 [note 4[d][i]] to these parties.

- [i] Pursuant to agreements [the "ColorectAlert™ License Agreements"] dated March 27, 1998, May 1, 1998 and October 23, 2001 between the Company and Dr. A.K.M. Shamsuddin [the "ColorectAlert™ Inventor"], the Company acquired a license, including the three existing United States and Japanese patents, for a technology that detects a carbohydrate marker associated with cancerous and pre-cancerous conditions ["ColorectAlert™"]. Pursuant to the terms of the agreements, the Company is required to make payments upon achieving certain research and development milestones as well as royalty payments based on revenues from sales of this technology. As at December 31, 2003, the Company has made milestone payments under the ColorectAlert™ License Agreements of approximately \$328,000. Future milestone payments, upon completion of specific milestones, could amount to as much as \$165,000. In addition, the Company granted warrants to purchase up to 100,000 common shares at exercise prices ranging from \$3.50 to \$4.50 per share to the ColorectAlert™ Inventor [note 4[d][ii]]. The 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.

- [ii] On June 19, 2001, the Company entered into an exclusive agreement with Diagnostic Chemicals Limited ["DCL"] to manufacture and supply the Company 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



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

the material breach by the other party or by the Company within 180 days notice or by DCL within 12 months notice.

- [iii] The Company entered into an agreement with Procyon Biopharma Inc. ["Procyon"] dated March 19, 2001, as amended [the "Procyon License Agreement"], whereby the Company has the right to complete the development, clinical trials and regulatory submission for the technology and is entitled 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 Company. Procyon is entitled to payments based on the completion of certain research and development milestones as well as a royalty payment based on sales of all mucous-based colorectal cancer tests. As at December 31, 2003, the Company has made milestone payments under the Procyon License Agreement of \$125,000. Future milestone payments, upon completion of specific milestones, could amount to as much as \$225,000. The Procyon License Agreement does not have a fixed termination date and it may be terminated upon written agreement of the parties, if the Company has not at that time engaged in any clinical work or product development in connection with the research and development of ColorectAlert™ or ColoPath™ or met minimum levels of sales of these products. In addition, the Company granted to Procyon warrants to purchase up to 75,000 common shares at an exercise price of \$4.50 per share in connection with this agreement. These warrants expire on March 19, 2004 [note 4[d][ii]].
- [iv] The Company has a research alliance with McMaster University ["McMaster"]. This research service agreement, dated October 31, 2000, requires the Company to provide research and development funding to McMaster in an amount of \$120,000 per year in support of the development of gene-based cancer products. The Company also has the right under this agreement for the use of laboratory facilities at McMaster. As at December 31, 2003, the Company has paid \$390,000 to McMaster under this agreement. The Company has granted or will grant warrants to purchase up to 10,000 shares per year at an exercise price of \$4.50 per share to McMaster under this agreement. This agreement has a termination date of October 31, 2005 and may be terminated earlier by the Company upon six months notice.
- [v] The Company entered into an agreement with Dr. S. Hakky dated August 30, 2000, as amended [the "Hakky License Agreement"], whereby the Company assumed responsibility for the development, clinical trials and regulatory submission for the technology and is entitled to develop, manufacture, market and distribute this technology exclusively on a worldwide basis. Further development of the technology was discontinued in 2003.
- [vi] On May 10, 1999 the Company entered into an agreement with X-Rite, Incorporated ["X-Rite"] to develop and supply the Company with a hand-held instrument and related software for Cholesterol 1,2,3™, for use in a professional setting. Pursuant to the terms of the X-Rite Agreement, the Company has agreed to purchase all of the worldwide requirements for color measuring devices and related software for use by the Company in marketing and selling Cholesterol 1,2,3™ systems in point-of-care applications in a professional setting from X-Rite. The term of the X-Rite Agreement is six years unless earlier terminated by either party upon the material breach by the other party or, at the option of X-Rite, if a certain minimum number of X-Rite instruments are not purchased. Further, under specific conditions, the Company may be required to make certain payments to X-Rite if less than a minimum number of X-Rite instruments have been purchased by the Company during a specified period following FDA clearance of Cholesterol 1,2,3™. As at December 31, 2003, other than for purchases of X-Rite instruments in the ordinary course of business, the Company has not made any such payments to X-Rite.



**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

**[c] Operating leases**

The Company has future minimum annual lease payments under operating leases for its office premises as follows:

	\$
2004	78,000
2005	31,000
	109,000

**7. CONSOLIDATED STATEMENTS OF CASH FLOWS**

Changes in non-cash working capital balances related to operations comprise:

	Year ended December 31, 2003 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
Prepaid expenses and other receivables	(99,063)	(103,452)	(66,935)
Investment tax credits receivable	91,000	(60,000)	(131,000)
Accounts payable and accrued liabilities	(46,907)	230,881	7,070
Advance collaboration funding		(36,588)	(19,000)
Deferred revenue	(6,900)	100,000	
	(61,870)	130,841	(209,865)

Excluded from the consolidated statement of cash flows for the year ended December 31, 2003 is the issuance of warrants paid as consideration for services of \$6,000 as described in notes 4[c] and 4[d][i].

Excluded from the consolidated statement of cash flows for the year ended December 31, 2002 is the issuance of compensation options issued in connection with the private placement of common shares of \$188,400, the issuance of common shares for consideration of share purchase loans of \$165,000 as described in note 4[d][i] and the issuance of warrants paid as consideration for services of \$2,165 as described in notes 4[c] and 4[d][i].

For the 11-month period ended December 31, 2001, excluded is the issuance of warrants paid as consideration in acquiring certain acquired technology of \$305,000 and services of \$5,000. Included as a purchase of capital assets is an amount of \$84,782 that was included in accounts payable and accrued liabilities for the year ended January 31, 2001.

**8. RECONCILIATION OF CANADIAN TO UNITED STATES**

**GENERALLY ACCEPTED ACCOUNTING PRINCIPLES**

The Company prepares its consolidated financial statements in accordance with Canadian GAAP, which, as applied in these consolidated financial statements, conforms in all material respects to U.S. GAAP, except as follows:

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

If U.S. GAAP were followed, the effects on the consolidated statements of loss and deficit would be as follows:

	Year ended December 31, 2002 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
<b>Net loss for the period [Canadian GAAP]</b>	<b>(4,062,711)</b>	(4,018,262)	(3,245,206)
Adjustments			
Amortization of acquired technology [a]	<b>113,393</b>	141,742	126,138
Acquired technology expense [a]			(686,507)
Fixed stock options granted to employees [b]		(5,625)	(7,500)
Fixed stock options granted to non-employees [c]		(57,521)	(48,923)
Performance stock options [d]		(931,474)	(254,838)
Share purchase plan [e]			(45,744)
<b>Net loss and comprehensive loss for the period [U.S. GAAP] [f]</b>	<b>(3,949,318)</b>	(4,871,140)	(4,162,580)
<b>Basic and diluted loss per share [U.S. GAAP]</b>			
	<b>\$ (0.19)</b>	\$ (0.24)	\$ (0.22)
<b>Weighted average number of common shares outstanding</b>			
Basic and diluted	<b>20,967,677</b>	20,406,733	19,097,390
<b>Excluded from the diluted weighted average number of common shares outstanding are</b>			
Employee stock options			533,982
Warrants			4,188

Basic loss per common share is determined using the weighted average number of common shares outstanding during the periods. As a result of the net losses for the years ended December 31, 2003 and 2002 and the 11-month period ended December 31, 2001, the potential dilutive effect of the exercise of stock options and warrants was anti-dilutive, and therefore has not been included in the calculation of diluted loss per share.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

Consolidated balance sheet items, which would vary under U.S. GAAP, are as follows:

	December 31, 2003 \$	December 31, 2002 \$	December 31, 2001 \$
<b>ASSETS</b>			
Acquired technology, net [a]			
	7,620,454	10,812,417	8,635,250
<b>SHAREHOLDERS' EQUITY</b>			
Capital stock	28,789,296	28,399,039	22,850,029
Additional paid-in capital	2,855,856	1,705,634	724,250
Warrants	312,200	496,000	310,000
Deferred compensation	(610,608)	(65,091)	(102,711)
Deficit accumulated during the development stage	(24,362,038)	(20,412,720)	(15,541,580)
	6,984,706	10,122,862	8,239,988

If U.S. GAAP were followed, the effects on the consolidated statements of cash flows would be as follows:

	Year ended December 31, 2003 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
<b>OPERATING ACTIVITIES</b>			
Balance under Canadian GAAP	(3,395,714)	(3,549,567)	(3,238,696)
Acquired technology			(381,507)
<b>Balance under U.S. GAAP</b>	<b>(3,395,714)</b>	<b>(3,549,567)</b>	<b>(3,620,203)</b>
<b>INVESTING ACTIVITIES</b>			
Balance under Canadian GAAP	2,943,778	(2,624,747)	(11,787)
Acquired technology			381,507

<b>Balance under U.S. GAAP</b>	<b>2,943,778</b>	<b>(2,624,747)</b>	<b>369,720</b>
--------------------------------	------------------	--------------------	----------------

---

**FINANCING ACTIVITIES**

Balances under Canadian GAAP of \$363,110 for the year ended December 31, 2003, \$5,731,386 for the year ended December 31, 2002 and \$1,278,328 for the 11-month period ended December 31, 2001 remain unchanged for U.S. GAAP purposes.

Since inception, the Company has not had significant revenue from operations. Accordingly, under Statement of Financial Accounting Standard ["FAS"] No. 7, "Accounting and Reporting by Development Stage Enterprise" ["FAS 7"], the Company is considered to be a development stage enterprise under U.S. GAAP. FAS 7 requires development stage enterprises to disclose additional financial statement information, which is presented in note 8[h].

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

In accordance with Section 3870 of the CICA Handbook, under Canadian GAAP, stock options and warrants awarded to non-employees in 2002 are accounted for using the fair value method. Under U.S. GAAP, the method of accounting for stock options is dependent upon who the option is issued to and whether the option is fixed or based on certain performance criteria. The Company follows Accounting Principles Board Opinion ["APB"] No. 25, "Accounting for Stock Issued to Employees" ["APB 25"] for awards issued to employees and FAS No. 123, "Accounting for Stock-Based Compensation" ["FAS 123"] for awards issued to non-employees. Accounting differences under Canadian GAAP and U.S. GAAP for stock options are described below.

**[a] Acquired technology**

Under U.S. GAAP, the Company's acquired technology, which is primarily comprised of patents and know-how which require regulatory approval to be commercialized and which has no proven alternative future uses, is considered in-process research and development and is immediately expensed upon acquisition in accordance with FAS No. 2, "Accounting for Research and Development Costs". The Company's acquired technology does not have an alternative future use given its specialized nature and limited alternative use. Under Canadian GAAP, the acquired technology is considered to be a development asset which is capitalized and amortized over its expected useful life.

**[b] Fixed stock options granted to employees**

APB 25 requires the Company to recognize compensation expense relating to the intrinsic value of the options when the market price of the underlying stock is greater than the exercise price of the Company's employee stock options on the grant date. Under Canadian GAAP, in accordance with Section 3870, the Company was not required to record compensation expense for stock options granted to employees until January 1, 2004. However, the Company elected to record the expense for the year ended December 31, 2003.

On January 1, 2003, the Company prospectively adopted the recommendations of Statement of Financial Accounting Standard ["SFAS"] No 123, "Accounting for Stock-based Compensation". Under the new policy, stock options awarded to employees on or after January 1, 2003 are accounted for using the fair value method. For stock options awarded to employees prior to January 1, 2003, pro forma disclosure of net loss and loss per share is provided below as if these awards were accounted for using the fair value method.

**[c] Fixed stock options granted to non-employees**

During the course of developing the Company's products, stock options were granted to consultants, researchers and advisors who are classified as non-employees. Stock options issued to non-employees are accounted for at fair value under the provisions of FAS 123. For options granted during 2002, this treatment is consistent with the provisions of CICA Section 3870. However, a Canadian-U.S. GAAP difference still arises on the amortization of fixed options granted to non-employees prior to January 1, 2002 as no compensation expense is recorded under Canadian GAAP for stock options granted to non-employees prior to January 1, 2002.

Fair value is determined using the Black-Scholes option pricing model, using assumptions as disclosed in note 8[g].

**[d] Performance stock options**

The Company granted performance stock options to employees that vest upon the achievement of certain milestones. In accordance with APB 25, such stock options are accounted for using the variable method of accounting until the performance milestone is achieved. Under variable accounting, if it is likely that the milestone will be met, the compensation associated is recalculated at each reporting date based on the current intrinsic value and amortized over the remaining vesting period. Under FAS 123, the fair value associated with

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

these performance stock options is presented as part of the pro forma disclosure. The only Canadian-U.S. GAAP difference arises on the amortization of performance stock options granted to non-employees prior to January 1, 2002 as no compensation expense is recorded under Canadian GAAP for stock options granted to non-employees prior to January 1, 2002.

**[e] Share purchase plan**

As discussed in note 4[f], effective March 22, 1999, the Company implemented a share purchase plan whereby the Company will match the value of the common shares purchased by its employees or directors by issuing from treasury an equal number of common shares. For purposes of U.S. GAAP, the fair value of common shares issued from treasury under the share purchase plan, as determined by the quoted market price, has been recorded as compensation expense. Under Canadian GAAP, the fair value of shares issued under the share purchase plan on or after January 1, 2002 has been recorded as compensation expense as they represent direct awards of stock.

**[f] Comprehensive income**

FAS 130, "Reporting Comprehensive Income", establishes standards for the reporting and display of comprehensive income and its components in general purpose financial statements. Comprehensive income is defined as the change in net assets of a business enterprise during a period from transactions and other events and circumstances from non-owner sources, and includes all changes in equity during a period. For the periods presented, the Company did not have any material transaction that would otherwise have had an impact on comprehensive income. As such, net loss for the period under U.S. GAAP is consistent with comprehensive income.

**[g] FAS 123 pro forma disclosures**

FAS 123 requires pro forma disclosures of net loss and loss per share, as if the fair value method, as opposed to the intrinsic value based method, of accounting for employee stock options had been applied.

The following table presents the Company's net loss and loss per share on a pro forma basis using the fair value method as determined by using the Black-Scholes option pricing model:

	Year ended December 31, 2003 \$	Year ended December 31, 2002 \$	11-month period ended December 31, 2001 \$
<b>Net loss for the period</b>			
U.S GAAP as reported	(3,949,318)	(4,871,140)	(4,162,580)
Pro forma stock-based compensation expense	(428,226)	(1,012,476)	(284,321)
<b>Net loss under U.S. GAAP - pro forma</b>	<b>(4,377,544)</b>	<b>(5,883,616)</b>	<b>(4,446,901)</b>
<b>Basic and diluted loss per share [U.S. GAAP]</b>			
As reported	\$ (0.19)	\$ (0.24)	\$ (0.22)
Pro forma	\$ (0.21)	\$ (0.29)	\$ (0.23)

The assumptions used to calculate the fair value of stock compensation expense using the Black-Scholes option pricing model are approximately as follows:





**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

	Year ended December 31, 2003	Year ended December 31, 2002	11-month period ended December 31, 2001
Expected volatility	54.3%	55.5%	59.1%
Risk-free interest rate	4.06%	4.56%	5.14%
Expected option life	5 years	5 years	5 years

Dividend yield assumption used for all periods presented was nil.

The Black-Scholes option pricing model, used by the Company to calculate option values, as well as other accepted option valuation models were developed to estimate fair value of freely tradable, fully transferable options without vesting restrictions, which significantly differ from the Company's stock option awards. These models also require highly subjective assumptions, including future stock price volatility and expected time until exercise, which greatly affect the calculated values. Accordingly, management believes that these models do not necessarily provide a reliable single measure of the fair value of the Company's stock option awards.

**[h] Development-stage disclosures**

FAS 7 requires development-stage companies to disclose, in addition to the same basic financial statements as presented in these consolidated financial statements, the following information:

[i] Consolidated statement of loss:

	Cumulative from inception on November 9 1992 \$
<b>EXPENSES</b>	
Research and development	10,405,436
General and administration	8,802,953
Acquired technology	1,147,257
Stock option compensation	6,816,303
Amortization	473,828
	27,645,777

**RECOVERIES AND OTHER INCOME**

Investment tax credits	1,670,856
Interest	1,549,063
Government grants	63,820

---

3,283,739

---

**Cumulative net loss from inception** (24,362,038)

---

---

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

[ii] Consolidated statement of cash flows:

	<b>Cumulative from inception on November 9 1992 \$</b>
Cash used in operating activities	(15,895,441)
Cash used in investing activities	(8,352,320)
Cash provided by financing activities	24,309,386
<b>Cumulative increase in cash and cash equivalents from inception</b>	<b>61,625</b>

[iii] The following represents the Company's cumulative statement of shareholders' equity determined in accordance with U.S. GAAP from inception:

	<b>Series I Preferred stock</b>		<b>Common stock</b>	<b>Additional paid-in capital</b>	<b>Warrants</b>	<b>Deferred compensation</b>	<b>Deficit incurred in the development stage</b>	<b>Total</b>
	<b>#</b>	<b>\$</b>	<b>#</b>					
			\$					
			\$					
			\$					
			\$					
			\$					

[000s]

[000s]

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

Balance, Nov. 9, 1992

Net loss for the period

				(374,703)	
				(374,703)	
Issued for cash					6,420
					255,004
					255,004

---

Balance, Jan. 31, 1994	6,420	255,004		(374,703)	(119,699)
Net loss for the year				(174,296)	(174,296)
Issued to extinguish a liability	720	240,000			240,000
Redemption	(2,337)	(130,695)	71,054		(59,641)

---

Balance, Jan. 31, 1995	4,803	364,309	71,054	(548,999)	(113,636)
Net loss for the year				(325,193)	(325,193)
Issued for cash	528	264,000			264,000
Issued on exercise of warrants		450	150,000		150,000
Issued for services		90	45,000		45,000
Issuance of stock options			2,420	(2,420)	
Amortization of deferred compensation					

202

202

---

Balance, Jan. 31, 1996

					5,871
					823,309
					73,474
					(2,218)
					(874,192)
Net loss for the year					20,373

Edgar Filing: IMI INTERNATIONAL MEDICAL INNOVATIONS INC - Form 20-F

						(497,576)
Issued for cash						(497,576)
						839
						559,500
						559,500
Issued on exercise of warrants						300
						100,000
						100,000
Issued for services						30
						15,000
						15,000
Issuance of stock options						23,736
						(23,736)
Amortization of deferred compensation						3,217
						3,217
Balance, Jan. 31, 1997	7,040	1,497,809	97,210	(22,737)	(1,371,768)	200,514

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

	Series I Preferred stock		Common stock		Additional paid-in capital		Warrants compensation		Deferred development stage		Deficit incurred in the	Total
	#	\$	#									
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
		\$										
	[000s]		[000s]									
Balance, Jan. 31, 1997			7,040	1,497,809	97,210		(22,737)	(1,371,768)	200,514			
Net loss for the year								(809,216)	(809,216)			
Issued on exercise of warrants			502	205,000					205,000			
Issued on conversion of debenture			2,000	500,000					500,000			
Issued for cash			2,267	1,478,942					1,478,942			
Issued on exercise of options			72	54,000	(53,880)				120			
Issuance of stock options					53,880		(53,880)					
Amortization of deferred compensation							65,144					65,144
Balance, Jan. 31, 1998			11,881	3,735,751	97,210		(11,473)	(2,180,984)	1,640,504			
Net loss for the year								(1,331,199)	(1,331,199)			
Issued on exercise of warrants			269	179,001					179,001			
Issued on purchase of technology			134	235,000					235,000			
Issued for cash	1,104	11										11
Issued on exercise of options			132	78,480	(1,440)				77,040			
Issuance of stock options					47,460		(47,460)					
Amortization of deferred compensation							48,905					48,905
Balance, Jan. 31, 1999	1,104	11	12,416	4,228,232	143,230		(10,028)	(3,512,183)	849,262			
Net loss for the year								(2,416,063)	(2,416,063)			
Conversion of Series I Preferred Shares	(559)	(6)							(6)			
Issued on conversion of Series I Preferred shares			559	932,436			(932,430)		6			
Issued under Special Warrants			1,200	1,034,159					1,034,159			
Issued on exercise of warrants			342	256,500					256,500			
Issued under share purchase plan [note 4[f]]			56	112,059					112,059			
Issued on exercise of options			172	119,853	(24,228)				95,625			
Issuance of stock options					117,600		(117,600)					
Amortization of deferred compensation							1,017,913					1,017,913
Balance, Jan. 31, 2000	545	5	14,745	6,683,239	236,602		(42,145)	(5,928,246)	949,455			



Amortization of deferred compensation

							311,260
							311,260
<hr/>							
Balance, Dec. 31, 2001	19,565	22,850,029	724,250	310,000	(102,711)	(15,541,580)	8,239,988
Net loss for the year						(4,871,140)	(4,871,140)
Issued on exercise of warrants <i>[note 4[d]]</i>	4	25,000					25,000
Issued under share purchase plan <i>[note 4[f]]</i>	10	47,219					47,219
Issued pursuant to private placement <i>[note 4[c]]</i>	1,200	5,282,196		188,400			5,470,596
Issued on exercise of options <i>[note 4[e]]</i>	378	449,640	(23,850)				425,790
<i>Issued for services [note 4[d][i]]</i>							
							(2,400)
							(2,400)
Issuance of stock options			1,005,234		(68,760)		936,474
Share purchase loans	(375)	(255,045)					(255,045)
Amortization of deferred compensation					106,380		106,380
<hr/>							
Balance, Dec. 31, 2002	20,782	28,399,039	1,705,634	496,000	(65,091)	(20,412,720)	10,122,862
<hr/>							





options were exercised at a price of \$0.00167 and 360,000 options expired upon termination of

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

employment. In connection with the Company's warrants, 502,000 common shares were issued for total proceeds of \$205,000 at an average exercise price of \$0.41 per warrant.

During the year ended January 31, 1999, 268,372 warrants were exercised at a price of \$0.667 and 128,750 warrants expired. Pursuant to the exercise of 45,000 of these warrants, share purchase demand loans of \$30,015 were made to two executive officers of the Company, bearing interest at 5% per annum and collateralized by 45,000 common shares. The Company also issued 132,000 common shares related to the exercise of stock options at an average exercise price of \$0.58. In addition, during the year, the Company created Series I Preferred Shares which are non-voting, carry no dividend rights, are convertible at the holder's option prior to October 31, 2002 on a one for one basis into common shares upon achievement of certain predetermined corporate milestones and are redeemable by the Company after October 31, 2002 for \$0.00001 per share. The Company issued 1,104,000 Series I Preferred Shares in replacement of stock options with the same rights and privileges. The Company has considered these Series I Preferred Shares as equivalent to performance based stock options and accordingly has recorded a compensation expense in the period when the performance milestones were met.

On May 27, 1998, the Company purchased an additional patent relating to a test to measure skin cholesterol, for a combination of cash and 14,286 common shares valued at \$1.75 per share for total consideration of \$50,000. In addition, in connection with the purchase of the remaining 11% of 2860601 Canada Inc. ["2860601"] that it did not already own, the Company paid a combination of cash and 120,000 common shares valued at \$1.75 per share for a total consideration of \$260,750. As the only significant asset held by 2860601 was technology, the entire value of the incremental purchase was ascribed to acquired technology.

During the year ended January 31, 2000, the Company issued 342,000 common shares for total proceeds of \$256,500 in connection with options granted in October 1997 to the agent of the Company's initial public offering. The Company issued an aggregate of 55,774 common shares to employees under the share purchase plan for no additional consideration, which were valued at \$112,059 and included as a compensation expense. In addition, upon the successful achievement of performance milestones, the Company issued 559,000 common shares to employees for no additional consideration pursuant to the conversion of previously issued Series I Preferred Shares. Subsequent to January 31, 2000, on March 17, 2000, the remaining milestones relating to the Series I Preferred Shares were achieved and the 545,000 preferred shares were converted into common shares for no additional consideration. For accounting purposes, a compensation expense of \$932,430 and \$2,896,740 was recorded in each respective period. On September 30, 1999, pursuant to a prospectus filed with the Ontario Securities Commission, the Company issued 1,200,000 common shares and 600,000 common share purchase warrants for net proceeds of \$1,034,159 after deducting agents' commissions, fees and other costs associated with the offering totalling \$165,841. Each common share purchase warrant entitled the holder to acquire one common share at a price of \$1.25 per share. The Company also granted the agent and sub-agent compensation options to purchase up to 120,000 common shares at an exercise price of \$1.25. Total stock options exercised during the year was approximately 172,000 for \$119,853, of which \$95,625 was received in cash.

For the years ended December 31, 2003 and 2002 and the 11-month period ended December 31, 2001, see note 4 for a description of the Canadian-U.S. GAAP differences.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

[iv] Common stock

	<b>Cumulative from inception on November 9, 1992</b>	
	<b>Number of shares</b>	
	#	\$
Shares issued for cash	12,153,917	8,204,682
Shares issued for services	124,202	85,000
Shares issued on purchase of technology	134,286	235,000
Exercise of stock options	761,850	839,215
Shares issued under the share purchase plan for no cash consideration	93,522	261,641
Warrants exercised for cash	2,868,230	2,188,112
Special warrants exercised for cash	4,357,895	12,169,060
Shares redeemed for cash	(2,337,000)	(130,695)
Shares issued on conversion of debenture	2,000,000	500,000
Shares issued on conversion of Series I Preferred Shares	1,104,000	4,437,281
	<b>21,260,902</b>	<b>28,789,296</b>

**[i] Additional consolidated balance sheet information**

Accounts payable and accrued liabilities consisted primarily of accruals related to clinical trials of \$142,000 [2002 - \$211,886; 2001 - \$204,739] and amounts owing to trade creditors of \$302,435 [2002 - \$276,303; 2001 - \$116,959].

In accordance with Canadian GAAP, the Company's cash and cash equivalents and short-term investments are carried at the lower of cost or market based on quoted market prices. Under U.S. GAAP, these investments would have been classified as held-to-maturity and would be recorded at amortized cost. There is no significant difference between cost under Canadian GAAP and amortized cost under U.S. GAAP. Accrued interest is included in the short-term investments balance, which in total approximates fair value.

**[j] Recent accounting developments**

In November 2002, FASB issued Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others" ["Interpretation 45"]. Interpretation 45 requires disclosure by a guarantor regarding its obligations under certain guarantees it has issued, effective December 31, 2002. As at December 31, 2003, the Company had no guarantees requiring disclosure. Interpretation 45 also requires recognition of a liability for the fair value of its obligations under guarantees issued after December 31, 2002. The Company has reviewed its policies and determined there is no impact as a result of the Company adopting these pronouncements.

In December 2002, FASB issued SFAS No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure" ["FAS 148"]. FAS 148 amends FAS No. 123 to provide alternative methods of transition to FAS No. 123's fair value method of accounting for stock-based compensation. The Company has reviewed its policies and determined there is no impact as a result of the Company adopting these pronouncements.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

December 31, 2003

[In Canadian dollars, unless otherwise noted]

FASB issued Interpretation No. 46, "Consolidation of Variable Interest Entities" [ Interpretation 46 ] in December 2003. Similar to AcG-15 in Canadian GAAP, Interpretation 46 provides criteria and guidelines to determine whether an entity is a variable interest entity to the Company for consolidation purposes. The Company will adopt the requirements of Interpretation 46 and is currently reviewing its impact.

**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, 448048 Ontario Inc. and First United Real Estate Investors, Inc. dated May 1, 2000. Previously filed as an exhibit to the Corporation's Registration Statement on Form 20-F filed on June 18, 2002 (File No. 001-31360).
- 4.7\* 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 8, 2004 (File No. )
- 4.11 Code of Ethics/Code of Business Conduct
- 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.

/s/ RONALD HOSKING

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

---

**Ronald Hosking**  
**Vice President, Finance and Chief Financial Officer**

Date: June 22, 2004