

## **MedMira Inc.**

Management's Discussion & Analysis

For the three month period ended October 31, 2012

## **Forward looking statements**

This document contains forward looking statements, such as statements regarding future sales opportunities in various global regions and financing initiatives that are based on current expectations of management. These statements involve uncertainties and risks, including MedMira Inc.'s (MedMira or the Company) ability to obtain and/or access additional financing with acceptable terms, and delays in anticipated product sales. Such forward-looking statements should be given careful consideration and undue reliance should not be placed on these statements.

The preparation of Management's Discussion and Analysis (MD&A) may require management to make estimates and assumptions that affect the reported amounts of assets and liabilities as of the date of the financial statements and the reported amount of revenue and expenses during the reporting period. Management bases estimates and judgments on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities. Actual results may differ from these estimates under different assumptions or conditions. Management believes the accounting policies, outlined in the Significant Accounting Policies section of its consolidated financial statements, affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

## **Introduction**

The following MD&A for the three months ended October 31, 2012 has been prepared to help investors understand the financial performance of MedMira in the broader context of the Company's strategic direction, the risk and opportunities as understood by management, and the key metrics that are relevant to the Company's performance. The Audit Committee of the Board of Directors has reviewed this document and all other publicly reported financial information for integrity, usefulness, reliability and consistency.

This document should be read in conjunction with the audited consolidated financial statements for the year ended July 31, 2012. Annual references are to the Company's fiscal years, which end on July 31. All amounts are expressed in Canadian dollars (CAD) unless otherwise noted.

Additional information about MedMira, this document, and the related quarterly financial statements can be viewed on the Company's website at [www.medmira.com](http://www.medmira.com) and are available on SEDAR at [www.sedar.com](http://www.sedar.com).

## **About MedMira**

MedMira is a biotechnology company engaged in the development and commercialization of rapid diagnostics and technology platforms. The Company is headquartered in Halifax, Nova Scotia, Canada and is listed on the TSX Venture Exchange (TSX-V) under the symbol MIR.

MedMira's patented rapid flow-through technology platform is the basis for the Company's current line of rapid diagnostics for infectious diseases. Diagnostic applications based on this technology platform are highly accurate, easy-to-use, and produce instant results – a strong advantage over most other rapid diagnostics on the market today.

MedMira's technology and growing portfolio of diagnostics demonstrate excellence in performance and quality in the highly competitive diagnostics industry. More than \$20 million has been invested in perfecting MedMira's core technology, which has proven itself time and time again with its excellent clinical performance and its success in rigorous evaluations and inspections, leading to regulatory approvals in the United States, Canada, European Union, and China, as well as ISO 9001:2008 and ISO 13485:2003 certifications. MedMira's rapid HIV test is the only rapid flow-through HIV test in the world to be approved by all of these major health regulators.

MedMira sells its rapid tests through a worldwide network of medical distributors and strategic business development partners with customers in all sectors of the healthcare industry, including laboratories, hospitals, point-of-care facilities, governments, and public health agencies.

## Intellectual property

The Company strives to protect its intellectual property in established and emerging markets around the world as warranted. MedMira's intellectual property portfolio for its rapid flow-through platform and the methodology behind its rapid diagnostics includes the following:

<i>Patent #</i>	<i>Title</i>	<i>Jurisdiction</i>
8,025,850	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States
7,531,362	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States
EP1417489	Rapid Diagnostic Device and Assay	Europe
EP1328811	HCV Mosaic Antigen Composition	Europe
ZL02819646.5	Rapid Diagnostic Device and Assay	China

The Company has three pending patents.

The Company's corporate and product brand names are protected by trademarks in the United States and Canada.

## Corporate update

During the first quarter, MedMira completed the last phase of its debt restructuring initiative. The Company announced on November 1, 2012, subsequent to the close of the quarter, that it had completed debt settlement arrangements with its debt holders and is no longer in a default position on any of its loans. Building on a debt reduction of \$11,834,592 completed in June 2012, the Company paid an additional \$312,992 to eliminate a further \$1,021,503 in debt. The debt holder agreements involve interest-only payments during the current fiscal year with no debt interest rates above three percent. The debt restructuring initiative has improved the overall operating position of MedMira, creating a stable financial platform to move many of the Company's business development and product commercialization activities forward.

In August 2012 the Company continued to build on its portfolio of business within the military sector by participating in the Military Health System Research Symposium (MHSRS). During the symposium, MedMira discussed and demonstrated its unique multiplex rapid diagnostics for an international audience. MedMira rapid diagnostics are critical tools in the treatment and care of individuals wounded in combat. MHSRS, the premier scientific meeting addressing the unique medical needs of the military combatant, was a collaborative environment where military medical care providers with deployment experience, Department of Defense (DoD) scientists, academia, and industry discussed and addressed the advancement of research and health care development in areas of Combat Casualty Care, Military Operational Medicine, Clinical and Rehabilitative Medicine, and Military Infectious Disease Research Programs.

MedMira's development and commercialization projects with the US military continue to advance towards clinical trials and product approval, with all major project milestones being met. The Company's work with the US Army is creating very positive business development dialog with other military organizations around the world.

The first quarter saw an increase in business development activity in Latin America and the Caribbean resulting in an increase in sales in these regions. Distribution partners in Panama and Colombia are finding success with the Company's Multiplo product line and business development discussions in various sectors, including the military, are ongoing throughout the region.

The Company, together with its strategic partners, continue a broad range of sales, marketing, and business development activities including market entry and development, public tender bidding, distribution channel development, and contract discussions in various regions of the world. This work moves at various paces and timelines on closing sales remain uncertain.

During the first quarter, MedMira began work on a major branding initiative. This ongoing organization-wide initiative involves the creation of an evolved brand identity, a re-designed and improved corporate website, new promotional videos, and development of a presence on various social media channels. Working with external design and digital media agencies and experts, the Company is evolving its brand to better reflect its innovative mindset and its core focus on technology and high quality testing solutions.

The new brand identity, implemented within this document, was launched in conjunction with the re-designed website subsequent to the close of the quarter. The logo symbol identifies with the Company name and the unique vertical flow-through technology that sets MedMira apart from other rapid diagnostics companies. The symbol also illustrates the advanced multiplex capabilities of MedMira's rapid testing solutions that deliver a minimum three test results on a single device. The new identity will also be applied to the Company's product portfolio of rapid testing solutions.

A central piece in MedMira's brand evolution is the redesigned and upgraded Company website, which boasts a new, modern look as well as quick and easy access to more in-depth product and company information. The new site includes product demonstration videos that illustrate how to use MedMira's rapid testing solutions in various environments, including point of care, laboratories and batch testing settings. These new videos are key sales and training tools for MedMira's partners and customers. The new website also includes an enriched section for investors, with an extensive Investor Kit.

## Financial results

### Basis of preparation and significant accounting policies

The basis of financial statement preparation and the significant accounting policies of MedMira are described in Notes 2 and 3 of the Company's October 31, 2012 condensed interim consolidated financial statements.

### Selected quarterly information

	Q1 2013	Q4 2012	Q3 2012	Q2 2012	Q1 2012	Q4 2011	Q3 2011	Q2 2011
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue	545	272	189	274	235	249	296	189
Cost of sales	377	167	58	63	88	155	147	101
<b>Gross profit</b>	<b>168</b>	<b>105</b>	<b>131</b>	<b>211</b>	<b>147</b>	<b>94</b>	<b>149</b>	<b>88</b>
Operating expenses	641	707	679	685	684	492	535	711
Other expenses	(616)	(8,835)	1,062	864	1,376	1,234	495	681
Net earnings (loss) before tax	143	8,233	(1,610)	(1,338)	(1,913)	(1,632)	(881)	(1,304)
Net earnings (loss) per share	0.001	0.024	(0.006)	(0.005)	(0.007)	(0.007)	(0.004)	(0.006)

### First quarter analysis

The following table compares the results of operations for the three months ended October 31, 2012 to the three months ended October 31, 2011.

	For the three months ended		Better (worse)
	31-Oct-12	31-Oct-11	
	\$	\$	
<b>Operations</b>			
Revenue	544,501	234,773	309,728
Cost of sales	<u>(377,463)</u>	<u>(88,294)</u>	<u>(289,169)</u>
<b>Gross profit</b>	<b><u>167,038</u></b>	<b><u>146,479</u></b>	<b><u>20,559</u></b>
<b>Operating expenses</b>			
Depreciation	(4,286)	(4,754)	468
Administrative expenses	(191,810)	(191,916)	106
Marketing expenses	(47,364)	(27,711)	(19,653)
Wages and salaries	(316,366)	(382,627)	66,261
Research and development expenses	<u>(80,790)</u>	<u>(76,751)</u>	<u>(4,039)</u>
Total operating expenses	<u>(640,616)</u>	<u>(683,759)</u>	<u>43,143</u>
<b>Results from operations</b>	<b><u>(473,578)</u></b>	<b><u>(537,280)</u></b>	<b><u>63,702</u></b>
<b>Non-operating income (expenses)</b>			
Net finance costs	(118,828)	(1,009,022)	890,194
Exchange rate gains (losses)	16,932	(366,903)	383,835
Other income	2,136	-	2,136
Gain on forgiveness of debt	<u>715,689</u>	<u>-</u>	<u>715,689</u>
Total non-operating income (expenses)	<u>615,929</u>	<u>(1,375,925)</u>	<u>1,991,854</u>
<b>Net income (loss)</b>	<b><u>142,351</u></b>	<b><u>(1,913,205)</u></b>	<b><u>2,055,556</u></b>

#### Operating revenue and gross profit

The Company recorded revenue from product sales and services in the quarter ended October 31, 2012 of \$544,501 as compared to \$234,773 for the same period last year. The increase in revenue was due to service revenue earned for research conducted for the US Army project. Gross profit for the quarter was \$167,038 compared to \$146,479 in the same period in 2011. The decrease in gross profit percentage to 31% from 64% is due to the lower margins on the US Army service revenue than on product sales. Revenue from product sales was \$201,687 during the three months ended October 31, 2012 (October 31, 2011 - \$234,773). The cost of product sales was \$87,435 during the three months ended October 31, 2012 (October 31, 2011 - \$88,294).

#### Operating expenses

Total operating expenses decreased to \$640,616 in the quarter ended October 31, 2012, compared to \$683,759 during the same period in 2011.

- Wages and benefits for the quarter ended October 31, 2012 was \$316,366, compared to \$382,627 for the same period in 2011. The decrease was due to increased allocation of labour costs to products produced during the quarter.
- Research and development expense for the quarter ended October 31, 2012 was \$80,790, compared to \$76,751 for the same period last year. Research expenses related to the US Army contract are recognized in cost of sales when the revenue is earned. During the quarter ended October 31, 2012, \$290,028 of the research costs incurred was recognized in a cost of sales (October 31, 2011 - \$nil). During the quarter ended October 31, 2012 research expenses were reduced by \$18,919 by grants received (October 31, 2011 - \$50,866).

- General and administrative (G&A) expenses were \$191,810 for the quarter ended October 31, 2012, compared to \$191,916 for the same period in 2011.
- Marketing expenses for the quarter ended October 31, 2012 was \$47,364 compared to \$27,711 for the same period last year. The increase in marketing expenses was driven by branding initiatives.

#### *Other expenses and income*

Other expenses and income, including interest and exchange loss, was a net gain of \$615,929 in the quarter ended October 31, 2012, compared to a net expense of \$1,375,925 during the same period in 2011.

- Financing expenses including interest expense decreased to \$118,828 in the quarter ended October 31, 2012, compared to \$1,009,022 for the same period last year. The decrease was the result of successful renegotiations of the company's debt to lower interest rates in the quarters ended October 31, 2012 and July 31, 2012. The company no holds no loans bearing greater than 3% interest.
- Exchange rate gain in the quarter ended October 31, 2012 was \$16,932 versus a loss of \$366,903 in the same period in 2011. The gain in the third quarter was due to a stronger Canadian dollar during the quarter ended October 31, 2012. The company has reduced its sensitivity to exchange gains and losses by settling the majority of US dollar denominated loans.
- In the quarter ended October 31, 2012 the company completed its debt settlement negotiations. As a result, the company had a one-time gain on the forgiveness of debt of \$715,689 (October 31, 2011 - \$nil).

#### **Geographic information**

The Company organizes and records the sales and distribution of its products and services based on major geographical territories around the world. The table below provides the geographic breakdown of revenue.

	<b>Product Revenue</b>		<b>Service Revenue</b>	
	<b>For the three months ended</b>		<b>For the three months ended</b>	
	<b>31-Oct-12</b>	<b>31-Oct-11</b>	<b>31-Oct-12</b>	<b>31-Oct-11</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
North America	136,383	132,293	342,814	-
Latin America and the Caribbean	63,829	2,967	-	-
Europe	1,475	380	-	-
Asia Pacific	-	99,133	-	-
<b>Total sales</b>	<b>201,687</b>	<b>234,773</b>	<b>342,814</b>	<b>-</b>

#### **Liquidity and capital resources**

##### *Cash and working capital*

The Company had a cash reserve of \$1,295,472 on October 31, 2012, as compared to \$2,416,809 on July 31, 2012. The Company's net working capital position as of October 31, 2012 was a deficit of \$0.8 million compared to the July 31, 2012 working capital deficit of \$8.1 million. The Company has incurred losses and negative cash flows on a cumulative basis since inception. For the three months ended October 31, 2012, the Company had net income of approximately \$0.1 million and negative cash flows from operations of \$0.9 million, compared to a net loss of \$1.9 million and negative cash flows from operations of \$0.4 million for the same period in 2011. Management is pursuing other financing alternatives to fund the Company's operations so it can continue as a going concern. Nevertheless, there is no assurance that this initiative will be successful.

*Operating activities*

MedMira generated negative cash flows from operations of \$853,453 for the three months ended October 31, 2012, compared to negative cash flows of \$363,828 for the three months ended October 31, 2011. The change in cash flow from operations was due to greater payments made to suppliers in the current period compared to last year.

*Financing activities*

Cash outflow from financing activities was \$251,337 for the three months ended October 31, 2012, compared to cash outflows of \$646,464 for the three months ended October 31, 2011. The higher cash outflow in 2011 was the result of higher cash payments against debt.

*Investing activities*

Cash outflow from investments increased to \$15,817 during the three months ended October 31, 2012, compared to \$3,343 for the three months ended October 31, 2011. The increase in investing cash outflow was the result of investments in information technology system upgrades.

**Debt**

As at October 31, 2012, the Company had loans payable with a carrying value of \$7.8 million compared to \$7.4 million at July 31, 2012. The Company's loans have an average payment term of 6 years with no interest rate exceeding 3%. As at October 31, 2012, none of the company's loans are in default.

Further discussions on liquidity and capital resources can be found in the Liquidity Risk section of this document, under Need for Additional Capital in the Risk and Uncertainties section in this document and in Notes 1 and 11 of the Company's October 31, 2012 condensed interim consolidated financial statements.

**Equity/Shares**

The Company is authorized to issue an unlimited number of common shares without nominal par value. During the nine months ended October 30, 2012, no common shares were issued. The number of issued and outstanding common shares on October 31, 2012 was 392,264,320. The Company is also authorized to issue an unlimited number of Series A preferred shares redeemable at \$0.01 per share after March 31, 2010, convertible into an equal number of common shares upon the Company meeting certain milestones. There were 5,000,000 Series A preferred shares issued and outstanding on October 31, 2012.

The Company had 5,050,000 outstanding stock options on October 31, 2012. The outstanding stock options have a weighted average exercise price of \$0.12 per share and a weighted average remaining term of 1.63 years. The number of outstanding warrants on October 31, 2012 was 236,119,500. The outstanding warrants have a weighted average exercise price of \$0.10 per share.

**Off balance sheet arrangements**

The Company was not party to any off balance sheet arrangements as of October 31, 2012 (October 31, 2011 - \$nil).

**Financial instruments – fair value**

The Company recognizes financial instruments based on classification. Depending on the financial instruments' classification, changes in subsequent measurements are recognized in net loss or other comprehensive loss. The Company has implemented the following classifications:

*Financial assets*

- Cash and bank balances: Classified as available for sale and recorded at fair market value. Changes in fair value for the

year are recorded in net loss.

- Trade and other receivables: After initial fair value measurement, trade and other receivables are measured at amortized cost using the effective interest method.

#### *Financial liabilities*

- Total bank indebtedness and current portion of debt, deferred income, trade and other payables, provision for royalty: After initial fair value measurement, these financial liabilities are measured at amortized cost using the effective interest method.

Management believes the carrying value of accounts receivable, bank indebtedness, and accounts payable and accrued liabilities approximate fair value at the year-end due to their short-term nature.

Fair value estimates are made at a specific point in time based on relevant market information. These estimates involve uncertainties and matters of significant judgement and cannot be determined with precision. Change in assumptions and estimates could significantly affect fair values.

#### **Financial instruments – risk factors**

MedMira has exposure to the following risks from its financial instruments: liquidity risk, credit risk, currency risk, and interest rate risk. Senior management monitors risk levels and reviews risk management activities as necessary.

#### *Liquidity risk*

The Company manages liquidity by forecasting and monitoring operating cash flows and through the use of revolving credit facilities and share issuances.

The Company has incurred losses and negative cash flows from operations on a cumulative basis since inception. For the three months ended October 31, 2012, the Company realized a net income of approximately \$0.1 million (October 31, 2011 – net loss \$1.9 million), consisting of a net loss from operations of \$0.5 million (October 31, 2011 - \$0.5 million), a gain on forgiveness of debt of \$0.7 million (July 31, 2011 – \$nil), and other non-operating losses of \$0.1 million (July 31, 2011 - \$1.4 million). Negative cash flows from operations were approximately \$0.9 million (October 31, 2011 - \$0.4 million). As at October 31, 2012, the Company had an accumulated deficit of approximately \$70.4 million (July 31, 2012 - \$70.6 million). In addition to its on-going working capital requirements, the Company must secure sufficient funding for its research and development programs for existing commitments, including its current portion of loans of approximately \$0.4 million. These circumstances lend doubt as to the ability of the Company to meet its obligations as they come due and, accordingly, the appropriateness of the use of accounting principles applicable to a going-concern.

To date the Company has relied on temporary funding advanced by key investors and allocation of limited resources through the management of payables. Management is pursuing other financing alternatives to fund the Company's operations, so it can continue as a going-concern. Management plans to secure the necessary financing through new equity and debt arrangements and is pursuing dramatic increases in sales revenue. Nevertheless, there is no assurance that this initiative will prove successful.

#### *Credit risk*

Credit risk refers to the risk that counterparty will default on its contractual obligations resulting in financial loss to the Company. The company mitigates this risk by requiring a 50% down payment on most orders at the time of purchase, and the remaining 50% prior to shipment. The receivables balance of \$503,591 represents primarily receivables on research initiatives and trade receivables from sale of the Company's products. Historically, there have been no collection issues and the Company does not believe it is subject to any significant concentration of credit risk.

*Currency risk*

MedMira receives most of its revenues in foreign currencies and incurs expenses in US and Canadian currencies. As a result, the Company is subject to uncertainty as foreign exchange rates fluctuate. The Company's US dollar (USD) denoted debt is US \$50,000 at October 31, 2012 (July 31, 2012 - \$75,000). The exchange fluctuations from year to year have accounted for a significant portion of the company's exchange gain and loss. Sales are, for the most part, in USD, however, they are recorded at the exchange rate prevailing on or near the transaction date and collected in a timely manner.

The Company also experiences currency exposure resulting from balance sheet fluctuations of US-denominated cash, accounts receivable, accounts payable and US-denominated promissory notes.

MedMira mitigates this currency risk by maintaining a balance of USD currency which is used to pay down US-denominated liabilities and replenishes the balance through US-denominated revenues.

A one cent change in the USD/CAD exchange rate would have an estimated impact on revenue of \$5,000.

*Interest rate risk*

The Company is not exposed to interest rate risk as it borrows funds at fixed rates.

**Related party transactions**

The following transactions occurred within the normal course of operations during the three months ended October 31, 2012:

- A director of MedMira received payments of \$19,615 in the quarter ended October 31, 2012 (October 31, 2011 – \$nil) for the establishment of a subsidiary.

The following balances with related parties were outstanding at October 31, 2012:

- A receivable balance of \$8,630 is owed to MedMira by a company which is presided over by a director (July 31, 2012 – \$8,630).
- An accounts payable balance of \$10,997 is owed to a director of MedMira (July 31, 2012 - \$22,083).
- A royalty provision is owed to OnSite Lab Holding AG of \$422,915 (July 31, 2012 – \$401,433).

**Internal control systems and disclosure controls**

To ensure the integrity and objectivity of the data, management maintains a system of internal controls comprising of written policies, procedures and a program of internal reviews which provides reasonable assurance that transactions are recorded and executed in accordance with its authorization that assets are properly safeguarded and that reliable financial records are maintained.

Management is currently updating existing standardized processes to improve internal controls and reduce compliance costs. The updated controls will help improve timeliness and accuracy of financial records as well as continue to ensure that the Company's assets are properly safeguarded.

Disclosure controls and procedures within MedMira have been designed to provide reasonable assurance that all relevant information is identified to the Disclosure Committee to ensure appropriate and timely decisions are made regarding public disclosure.

Management, under the supervision of the Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's internal control over financial reporting and based on this evaluation, has concluded that internal control over financial reporting was effective as of October 31, 2012.

Due to inherent limitations, internal control over financial reporting and disclosure controls can provide only reasonable assurances and may not prevent or detect misstatements. Furthermore, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The Audit Committee of the Board of Directors of MedMira reviewed this MD&A, and the consolidated financial statements of MedMira for October 31, 2012 and MedMira's Board of Directors approved these documents prior to release.

## **Risk and uncertainties**

The Company's base of activity has expanded to manufacturing products for distribution in international markets, making it difficult to accurately predict future operating results. Actual future results may differ significantly in any forward-looking statements. Currently, the Company is not making sufficient sales to be self-sustaining. As a result, the Company's financial condition, business and operations, and intellectual property are exposed to a variety of risk factors. These risks include, but are not limited to, the following:

### **Risks and uncertainties related to the Company's financial condition**

#### *Need for additional capital*

Cash generated from operations is insufficient to satisfy working capital and capital expenditure requirements, and the Company is operating with a substantial working capital deficit. The Company will need to secure additional financing in the near term in order to continue as a going concern which may include the sale of additional equity or debt securities or obtaining additional credit facilities. In recent quarters, the Company has relied on temporary funding advanced from key investors. There can be no assurance that this source of funding will continue to be available on acceptable terms, and additional capital may not be available on satisfactory terms, or at all. Management is pursuing other financing alternatives to fund the Company's operations so it can continue as a going-concern.

The Company intends to continue to explore opportunities to enter into supply agreements, joint venture relationships, and other special purpose vehicles with third parties from time to time in order to continue to commercialize its patent pending technology and other intellectual property. Such arrangements may include the issuance of equity or debt securities of the Company, subject to compliance with the applicable requirements of the Canadian securities regulatory authorities and the TSX-V.

Any additional equity financing may result in the dilution of shareholders, and debt financing, if available, may include restrictive covenants. MedMira's future liquidity and capital funding requirements will depend on numerous factors including:

- the extent to which new products and products under development are successfully developed, gain market acceptance and become and remain competitive;
- the costs and timing of further expansion of sales, marketing and manufacturing activities and facilities needs;
- the timing and results of clinical studies and regulatory actions regarding potential products; and
- the costs and timing associated with business development activities, including potential licensing of technologies patented by others.

Continued operations will be contingent on generating sufficient revenues or raising additional capital or debt financing. There is no assurance that these initiatives will be successful.

#### *Fluctuations in revenue*

The Company's quarterly and annual revenues may fluctuate due to several factors, including seasonal variations in demand, competitive pressure on average selling prices, customer order patterns, the rate of acceptance of the Company's products, product delays or production inefficiencies, regulatory uncertainties or delays, costs and timing associated with business development activities, including potential licensing of technologies, international market conditions and variations in the timing and volume of distributor purchases. The healthcare industry traditionally is not impacted by seasonal demand. The impact of one or a combination of several of these factors could have a significant adverse effect on the operations of the Company. In addition, changes in existing collaborative relationships, as well as the establishment of new relationships, product licensing and other financing relationships, could materially impact the Company's financial position and results from operations.

#### *Effects of inflation and foreign currency fluctuations*

A significant portion of the Company's revenue and expenses are in U.S. dollars, and therefore subject to fluctuations in exchange rates. There is a risk that significant fluctuations in exchange rates may impact the Company's ability to sell its products and, thereby, have a material adverse impact on the Company's results of operations.

#### *Possible volatility of share price*

The stock market has from time to time experienced significant price and volume fluctuations that may be unrelated to the operating performance of the Company. In addition, the market price of the Company's common shares, like the share prices of many publicly traded biotechnology companies, has been highly volatile. Announcement of technology innovations or new commercial products by the Company or its competitors, developments or disputes concerning patent or proprietary rights, publicity regarding actual or potential medical results relating to products under development by the Company or its competitors, regulatory developments in both the U.S. and foreign countries, public concern as to the safety of biotechnology products and economic and other external factors, as well as period to period fluctuations in financial results may have a significant impact on the market price of the Company's common shares. It is likely that in some future quarter the Company's operating results will be below the expectations of the public market analysts and investors. In such event, the price of the Company's common shares would likely be materially adversely affected.

### **Risks and uncertainties related to the Company's business and operations**

#### *Lack of market acceptance*

MedMira's ability to market its diagnostic products will, in part, depend on its or its partners' ability to convince users that these products represent viable and efficacious diagnostic tests. There can be no assurance that MedMira will be successful in this regard.

#### *Competition*

The *in vitro* diagnostics market in which the Company participates is highly complex and competitive. It is comprised of both large healthcare companies that have substantially greater financial, scientific, and other resources than MedMira and a variety of international companies producing diagnostic products of varying quality. In the developed regions of the world with strong healthcare infrastructures, the *in vitro* diagnostics market for serious and emerging infectious diseases such as HIV and Hepatitis C has been focused on diagnostic tests using instrument based platforms designed for clinical laboratories. Diagnostic products designed for use in non-laboratory settings at the point-of-care or for use in laboratories or public health clinics using non-instrument based platforms for the screening and diagnosis of infectious diseases are becoming more mainstream in both the developed and developing regions of the world. Competition in this sector of the

market is intense and is expected to increase. Many of the companies have substantially greater resources available for development, marketing and distribution of these products than does MedMira.

*Significant development effort required*

Products currently under development by MedMira require additional development, testing and investment prior to any final commercialization. There can be no assurance that these products or any future products will be successfully developed, prove to be safe and effective in clinical trials, receive applicable regulatory approvals, be capable of being produced in commercial quantities at reasonable costs or be successfully marketed. The long-term success of MedMira must be considered in light of the expenses, difficulties and delays frequently encountered in connection with the development of new technology and the competitive and highly regulated environment in which MedMira operates.

*Uncertainties in sales cycles in target markets*

MedMira markets and distributes its products to both developed and developing regions of the world. Sales cycles in developed regions of the world are somewhat conventional, however, timing of registrations and other activities surrounding the sale of product into a specific market are unpredictable and highly dependent on third party and government organizations to complete certain processes before a sales transaction can take place. In developing regions of the world where MedMira and its strategic partners are working to close deals, the sales cycle timing is highly uncertain given a number of factors including political and economic turmoil, as well as bureaucratic processes necessary to do business in these regions.

*High degree of regulation*

MedMira operates in a highly regulated industry and is subject to the authority and approvals of certain regulatory agencies, including Health Canada, the US Food and Drug Administration (FDA), the State Food and Drug Administration (SFDA) in China, the Notified Body in the European Union and applicable health authorities in other countries, with regard to the development, testing, manufacture, marketing and sale of its products. The process of obtaining such approvals can be costly and time consuming, and there can be no assurance that regulatory approvals will be obtained or maintained. Any failure to obtain (or significant delay in obtaining) or maintain Health Canada, FDA, Notified Body or SFDA approvals (or, to a lesser extent, approval of applicable health authorities in other countries) for MedMira's new or existing products could materially adversely affect MedMira's ability to market its products successfully and could therefore have a material adverse effect on the business of MedMira.

*Ability to retain and attract key management and other experienced personnel*

Since its inception, the Company has been, and continues to be, dependant in its ability to attract and maintain key scientific and commercial personnel upon whom the Company relies for its product innovations and commercialization programs. Loss of key personnel individually or as a group could have significant adverse impact on the Company's immediate and future achievement of operating results.

*Limited sales and marketing resources and reliance on key distributors to market and sell the Company's product*

Any revenues received by the Company will be dependent on the efforts of third parties and there can be no assurance that such efforts will be successful. Failure to establish sustainable and successful sales and marketing programs with effective distributor support programs may have a material adverse effect on the Company.

Commercialization of the Company's products is expensive and time consuming. In the USA, an exclusive distribution relationship has been established with American Health Diagnostics to market and sell the Company's products. The Company will rely on the joint sales efforts of its exclusive US distributor and their sub-distributors Cardinal Health, a Fortune 100 company, and VWR International to distribute MedMira's *Reveal*<sup>™</sup> G3 Rapid HIV-1 Antibody Test product line.

Outside the US, the Company pursues collaborative arrangements with established pharmaceutical and distribution companies for marketing, distribution, and sale of its products.

In China, MedMira has formed a strategic partnership with Triplex to market and distribute the Company's rapid HIV test within the assigned territory. This strategic partnership also encompasses the assembly and packaging of final product components.

In Africa, MedMira works with a number of strategic partners, including Vitest AG, Advance Aid, and MultiMED, all covering various regions and sectors of Sub-Saharan Africa, North Africa, and the Middle East.

If any of the Company's distribution agreements are terminated and the Company is unable to enter into alternative agreements, or if the Company elects to distribute new products directly, additional investment in sales and marketing resources would be required which would increase future selling, general and administrative expenses. The Company has limited experience in direct sales, marketing and distribution of its products. A failure of the Company to successfully market its products would have a material and adverse effect on the Company.

#### *Manufacturing capabilities and scale-up*

The Company must manufacture its products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. If it is unable to manufacture or contract for such capabilities on acceptable terms for its products under development, MedMira's plans for commercialization could be materially adversely affected.

MedMira's manufacturing facilities are, or will be, subject to periodic regulatory inspections by the FDA, Notified Body, SFDA and other regulatory agencies and these facilities are subject to Quality System Regulations requirements of the FDA and other standards organizations. MedMira may not satisfy such regulatory or standards requirements, and any failure to do so would have a material adverse effect on the Company.

In addition, production and scale-up of manufacturing for new products may require the development and implementation of new manufacturing technologies and expertise. Manufacturing and quality control problems may arise as the Company attempt to scale-up manufacturing and such scale-up may not be achieved in a timely manner or at commercially reasonable cost, or at all.

#### *Rapidly changing technology*

The *in vitro* diagnostic testing field as a whole is characterized by rapidly advancing technology that could render MedMira's products obsolete at any time and thereby adversely affect the financial condition and future prospects of the Company.

#### *Uncertainties regarding healthcare reimbursement and reform*

The future revenues and profitability of diagnostic companies as well as the availability of capital may be affected by the continuing efforts of government and third party payers to contain or reduce costs of healthcare through various means. For example, in certain foreign markets, pricing or profitability is subject to government control. In the US, there has been, and the Company expects that there will continue to be, a number of federal and state proposals to implement similar government controls. While the Company cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of such proposals could have a material adverse effect on the Company's results of operations.

#### *Product liability*

MedMira may be subject to claims of personal injury and could become liable to clinical laboratories, hospitals and patients for injuries resulting from the use of its products. MedMira could suffer financial loss due to defects in its

products and such financial loss together with litigation expenses could have a material adverse effect on its operations. MedMira has obtained product liability insurance to protect against possible losses of this nature. However, no assurance can be given that such insurance will be adequate to cover all claims or that MedMira will be able to maintain such insurance at a reasonable cost.

#### **Risks and uncertainties related to the Company's intellectual property**

##### *No assurance of patent protection*

MedMira has filed patent applications in the US, Canada, China, and other foreign countries relating to various aspects of its rapid diagnostic platform, processes, reagents, and equipment. Although MedMira's management believes that the patents for which the Company applied may be issued, there can be no such assurance, nor can MedMira assure that competitors will not develop functionally similar or superior diagnostic testing devices. Moreover, there is a question as to the extent to which biotechnology discoveries and related products and processes can effectively be protected by patents. The law regarding the breadth or scope of biotechnology patents is new and evolving. No assurance can be given that, if a patent issued to MedMira is challenged, it will be held valid and enforceable or will be found to have a scope sufficiently broad to cover competitors' products or processes. The cost of enforcing MedMira's patent right, if any, in lawsuits that it may bring against infringers may be significant and could limit MedMira's operations.

##### *Possible patent infringement*

The extent to which biotechnology discoveries and related products and processes can be effectively protected by patents and be enforceable is uncertain and subject to interpretation by the courts. The technologies, products, and processes of MedMira may be subject to claims of infringement on the patents of others and, if such claims are successful, could result in the requirement to access such technology by license agreement. There can be no assurance that such licenses would be available on commercially acceptable terms. If MedMira is required to acquire rights to valid and enforceable patents but cannot do so at reasonable cost, MedMira's ability to manufacture or market its products would be materially adversely affected. The cost of MedMira's defence against infringement charges by other patent holders may be significant and could limit MedMira's operations.