

## **MedMira Inc.**

Management's Discussion & Analysis

For the six months ended January 31, 2024

## 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.

This MD&A contains statements that may constitute forward-looking statements about the Company's objectives, strategies, financial condition, results of operations, cash flows and businesses. These statements are "forward-looking" because they are based on current expectations, estimates, assumptions, risks, and uncertainties. These forward-looking statements are typically identified by future or conditional verbs such as "outlook", "believe", "anticipate", "estimate", "project", "expect", "intend", "plan", and terms and expressions of similar import. Such forward-looking statements are subject to a number of risks and uncertainties that include, but are not limited to: cyclical downturn; competitive pressures; dealing with business and political systems in a variety of jurisdictions; repatriation of funds or property in other jurisdictions; payment of taxes in various jurisdictions; exposure to currency movements; inadequate or failed internal processes, people or systems or from external events; dependence on key customers; safety performance; expansion and acquisition strategy; regulatory and legal risk; corruption, bribery or fraud by employees or agents; extreme weather conditions and the impact of natural or other disasters; shortage of specialized skills and cost of labour increases; equipment and parts availability, reputational risk; cybersecurity risk; market price and dilution of common shares and environmental regulation risk. Actual results could be materially different from expectations if known or unknown risks affect the business, or if estimates or assumptions turn out to be inaccurate. The Company does not guarantee that any forward-looking statement will materialize and, accordingly, the reader is cautioned not to place reliance on these forward-looking statements. The Company disclaims any intention and assumes no obligation to update any forward-looking statement, even if new information becomes available, because of future events or for any other reasons, except in accordance with applicable securities laws.

## Introduction

The MD&A was issued and approved by the Board of Directors on the April 1, 2024. The following MD&A for the six months ended January 31, 2024, 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, 2023. 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 ended January 31, 2024, 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).

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 January 31, 2024, consolidated financial statements, affect its more significant judgments and estimates used in the preparation of its consolidated financial statements.

## 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.

The patented MedMira Rapid Vertical Flow (RVF) Technology™ platform is the basis for the Company's line of rapid tests. Diagnostic applications based on this technology are highly accurate, easy-to-use, and produce instant results – a strong advantage over most other rapid diagnostics on the market today. These features are enhanced further with ability to deliver multiplex results on one test device with just one drop of specimen. The Company has created a new generation of rapid tests that are based on the need to provide immediate answers without increasing costs.

MedMira's technology platform and growing portfolio of diagnostic tools demonstrate excellence in performance and quality in the highly competitive diagnostics industry. More than \$30 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 for rapid diagnostic solutions in the United States (US Food and Drug Administration), Canada (Health Canada), the notified body in the European Union (CE Mark), and China (CFDA) and in a number of countries in Latin America, Africa, and Asia. The Company's quality system is ISO 9001 and ISO 13485 certified.

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

In addition to clinical diagnostics, the Company offers the Miriad™ product line to create new opportunities in the high value technology licensing sector. This business line allows the Company to monetize its award-winning technology and core capabilities, including R&D, product development, and regulatory proficiency. Miriad provides access to MedMira's RVF Technology for researchers, developers, and biotech companies on a license basis to facilitate the creation of new rapid tests or the transition of existing tests to this unique platform. Infiltrating new and different sectors of the diagnostic industry, such as veterinary and environmental, with the Company's technology, enables MedMira to build a higher degree of global awareness, generate new revenue streams, and provide a superior diagnostic platform to the market.

## 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 Vertical Flow Technology and the methodology behind its rapid diagnostics includes the following:

---

<i>Patent #</i>	<i>Title</i>	<i>Jurisdiction</i>
9,164,087	Rapid Diagnostic Device, assay and multifunctional Buffer	United States
9,086,410	Downward or vertical flow diagnostic device and assay	United States
8,025,850	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States
8,287,817	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States

8,586,375	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States
7,531,362	Rapid Diagnostic Device, Assay and Multifunctional Buffer	United States
D706945	Diagnostic Device	United States
D706466	Diagnostic Device	United States
EP1417489	Rapid Diagnostic Device and Assay	Europe
ZL02819646.5	Rapid Diagnostic Device and Assay	China
2,493,616	Rapid Diagnostic Device, Assay and Multifunctional Buffer	Canada
11,353,450	Analyte Detection Using Raman Spectroscopy	United States
2,949,634	Analyte Detection Using Raman Spectroscopy	Canada

The Company has other patents pending patents in the US as well as two design patents in force or pending in eight markets. The Company's corporate and product brand names are protected by trademarks in the US and Canada.

The Company has recorded an impairment charge in previous fiscal years to write-down its intangible assets to a nominal value. There is no indication at the end of January 31, 2024, that this impairment has been reversed and thus the value of intangible assets on the balance sheet on January 31, 2024, is \$2 (July 31, 2023 - \$2).

## Corporate update

During Q2 FY2024, MedMira continued its focus on its regulatory and clinical trial work for five products related to Sexually Transmitted Infections (STI) and Respiratory Viruses. On December 13, 2023, the Company received the US FDA 510(k) clearance for the HIV-2 claim on the Reveal® G4 Rapid HIV 1/2 antibody test in the United States. With this regulatory clearance, MedMira continued its path to achieve Clinical Laboratory Improvement Amendments (CLIA) waiver which the Company anticipates to complete within the coming months.

With the new FDA approval and the overall changes in the market over the past years, the Company is able to sell to a broader customer base which shall be reflective in upcoming sales. In addition, the Company appointed a new Vice President of Business Development based in the United States to grow MedMira's brand and sales with the latest approved product and MedMira's unique Miriad product line. With this step, the Company is continuing its strategic plan to enhance its presence in North-America and grow its brand and revenue. A separate announcement will be issued on this matter.

In addition to its current work, the Company is awaiting two new grants sponsored by governmental third parties to access funding for two new product approvals in Canada and the US.

## Distribution and Sales

### MedMira (US) Inc.

In FY2024, the Company continued to expand its business development and sales team in the United States. In Q2 FY2024, MedMira appointed a new Vice President of Business Development with over 30 years of experience in the rapid test industry. A separate announcement will be made in Q3 FY2024. With this new addition, the Company has significantly increased its network and benefits from a US based business development and sales leadership. As result, MedMira continues its strategy to build a US based commercialisation team to maximize sales with the latest approved product and

its Miriad product line. With the upcoming additional revenue streams, the Company is committed to further expand its US operations and significantly grow its branding and market share.

### **Miriad – Unique Opportunity with a Unique Product**

The Company's Miriad product line is aimed at forensic laboratories, tissue and eye banks which is a unique niche market established by MedMira in 2016. Currently there are 300 registered tissue banks in the United States with an overall donor screening program of 2.5 million samples a year. Whereas this product line is already sold through MedMira's other non-exclusive distributors such as VWR, Medline Industries etc and has generated a loyal customer base, the Company forecasts a significant increase in Miriad sales in this financial year.

### **Distribution Partners**

Subsequent to Q2 FY2024, the Company has signed a new distribution agreement with an additional partner. With this the Company has engaged 4 out of the 5 largest distribution companies to promote and sell MedMira's current and future product. A joint announcement will be made in a separate Press Release.

### **Regulatory and Clinical Projects**

#### **HIV**

MedMira's 510(k) (FDA) approval for its Reveal® G4 Rapid HIV-1/2 antibody test on December 13, 2023 enabled the Company to commence with Clinical Laboratory Improvement Amendments (CLIA) waiver and launch the product the United States through its current and new distribution partners.

#### *Immediate advantages:*

Over the past years there has been a growing demand for rapid tests especially for infectious diseases. This is due to a number of reasons such as acceptance of rapid tests in more complex settings and the market's realisation of the comparable quality to standard systems and the cost-effectiveness of rapid tests in comparison to traditional testing. In addition, the higher prevalence rates contribute to the overall demand by health care providers for fast and affordable testing methods. These factors influenced changes to the acceptance criteria for certain providers such as hospitals and laboratories and with it allowed the possibility to purchase non-CLIA waived products. As result, the Company anticipates significant larger sales than previously expected.

#### *Next steps:*

MedMira is continuing its pursuit to achieve a Clinical Laboratory Improvement Amendments (CLIA) waiver for the Reveal® G4 Rapid HIV-1/2 antibody test. While CLIA waiver clinical trial process has commenced, the Company is further encouraged with the outstanding results achieved in its latest clinical trials. MedMira's latest study showed a sensitivity of 100% for HIV-1 and HIV-2. In addition, MedMira's Reveal® G4 rapid HIV antibody test achieved a flawless 100% specificity and was reactive in early HIV-1 infections and seroconverts. Once the CLIA waiver has been obtained, the Reveal® G4 Rapid HIV-1/2 will be available to all health care professionals and with it enable the Company to access the over USD\$350m annual market in the United States.

#### **Syphilis**

Subsequent to Q2 FY2024, the Company made the submission and since then has been working with the regulator on the additional clarifications and the extension of its intended use due to the increasing need in maternity screening. Over the past 10 years the infection rates increased by 73% among males whereas the rate among females increased by 773%. This resulted in a rise in congenital syphilis (syphilis transmitted during pregnancy to babies) and with it an increase in severe and life-threatening illnesses with up to 40% of babies being stillborn.

The Company's syphilis component showcased an overall performance of a PPA of 86.0% (95% CI 82.7-88.8%) and an NPA of 99.5% (98.8-99.8%). Notably, when the RPR titre was > 1:8 dilutions—indicative of an infectious case—the performance significantly improved to a PPA of 98.3% (95.7-99.3%) and an NPA of 99.5% (98.8-99.8%). This is particularly promising as it aligns with the marker for newly diagnosed infectious syphilis cases the study.

Furthermore, in a subset analysis involving specimens from women at various pregnancy stages, the MedMira's test exhibited high quality results. Specifically, the test accurately identified all previously syphilis-infected cases, demonstrated reliability in confirming negatives, and presented potential for maternity screening. In order to demonstrate this, the Company expanded its overall data pool with additional specimens including those from various pregnancy stages among negative and positive syphilis cases.

### **Hepatitis C**

MedMira filed its pre-submission for De Novo/510(k) Classification Request for its Reveal® Hepatitis C (HCV) Rapid Antibody Test. MedMira completed the Q-submission (Q220148) and received the agreement to proceed with the submission of its clinical and non-clinical protocols. In the first quarter of 2023, the Company is allowed to start the clinical trials and has identified the clinical trial and applied for the necessary IRB (Institutional Review Board). Whereas the U.S. Food and Drug Administration (FDA) downgraded the regulatory classification of HCV rapid antibody tests, the requirements for clinical performance, accuracy, and safety for these tests have not changed. MedMira has chosen a dual path which includes the De Novo/510 (k) and CLIA waiver in one trial. With this step, the Company is able to achieve both marketing classifications with one step.

### **COVID-19/Flu A & B/RSV**

During fiscal year 2023, the Company developed and validated the VYRA™ TriDemic Antigen Rapid Test which is a direct response to the rising infection rates of the Respiratory Syncytial Virus (RSV) and the increasing demand of a multiplex testing solution. The VYRA™ TriDemic test distinguishes the three respiratory viruses (SARS-CoV-2, Influenza and RSV) that exhibit similar symptoms, including fever, cough, and congestion. Based on MedMira's unique multiplex-testing RVF Technology®, the four-in-one test offers an immediate quality answer which decreases time to a diagnosis and determination of the appropriate treatment. Different to other rapid tests or conventional testing methods, VYRA™ TriDemic requires only one nasal swap sample and provides an immediate result.

There is a clear shift from a pandemic to an endemic situation (officially the WHO and regulators have not yet declared an end to the pandemic). At the same time, there is are significant less governmental support systems that distribute free products to the population. As a result, price pressure on manufacturers has notably decreased and implemented a transfer of costs to health care providers and patients. With this change, the overall demand for quality, speed and user experiences increases substantially. These two factors provide MedMira the opportunity to advocate its unique selling points as the fastest and ease-to-use alternative. In addition, the unique advantage of testing up-to four markers with one single swab, provides a further selling point to (paying) health care providers and customers. MedMira's aim is to provide flexible multiplexing solutions for the Company's distribution partners in order to have every competitive edge available to generate sales and obtain a significant market share.

Even though MedMira's HIV rapid test was the first Health Canada approved HIV rapid test, the overall demand for rapid test was insignificant in the Canadian market. This was mainly due to the low awareness of the equal quality compared to alternative testing systems. With the COVID-19 pandemic and the need for fast and cost-effective solutions, rapid tests became an acceptable testing method and with it changed the overall perception of the Canadian market. Rapid tests have proven to be a cost-effective alternative to slower and expensive traditional diagnostic methods without sacrificing quality. The opportunity to receive the necessary funding by the government of Canada and with it achieve the approval in Canada for a single Syphilis rapid test, was a significant chance to grow the MedMira brand in its home country.

## Research

The Company has developed and validated a new and unique STI prototype for the John Hopkins School of Medicine, Division of Infectious Diseases. As a result the Company is able to enter the next phase by starting clinical trials with the aim to achieve FDA approval. This step is entirely funded externally and will enable MedMira to launch the first multiplex saliva based STI rapid test. With this, the Company expands its STI product offering by providing alternative sample collection methods aimed at screening programs and potentially home-users.

The budget for the next steps have been finalised and are awaiting the allocation by the funding agency and shall be finalised within Q3 2024.

In Q1 FY2024, MedMira signed a product development agreement with a US based governmental agency. The product will be based on MedMira's unique RVF® Medduo platform which allows the detection of up-to 8 biomarkers in one test. The Company completed the prototype and provided samples for testing to the client. Subsequent to Q2 FY2024, MedMira received positive feedback and shall enter into the next discussions regarding Phase 2 which includes the final product development for commercialisation.

---

## Technology

During Q2 FY2024, the Company continued its work on the first commercial prototype of its MiROQ™ system. In partnership with a Canadian third party, the Company is continuing the finalisation of the design, software and shall commence on additional testing in the coming months. Subsequent to Q2 FY2024, MedMira received on March 13, 2024 the Canadian patent (number 2,949,634) for its MiROQ™ system. This is in addition to the U.S. patent (number 11,353,450) received in 2022.

MedMira's latest novel diagnostic system allows for accessible and efficient diagnostic tools for quantitative results in minutes. The user-friendly interface combined with automated interpretation allows for an expansion of MedMira's current RVF-based tests and can provide a pathway to significantly increase the technology's multiplexing abilities. The combination of the RVF and Surface-Enhanced Raman Spectroscopy\* (SERS) technology, creates MedMira's patented novel high quality and cost-effective tool for the next generation - MIROQ™. This enables the amplification of the results produced by MedMira's RVF-based rapid tests by creating a unique 3D structure with remarkable reproducibility that is yielded in a linear plot ( $R^2 = 0.98$ ). The new addition to MedMira's patent family creates perfect collaboration to expand its access in both the clinical immunoassay and the Point-of-Care markets, opening new doors into the evolving diagnostic landscape by providing both qualitative and quantitative test results in minutes.

The company developed the first prototype system in 2014 and went through extensive verification and validation performed by our academic partners here in NS, Canada. These findings were published in the Journal of Analytical Chemistry in November 2016 and describe the performance and efficiency of this technology to be on par with traditional expensive laboratory testing solutions which are generally limited to high complexity labs. This patented system with the proprietary build-in data capture and analysis software allows for immediate analysis of any positive (reactive) results within 1 min. This is in contrast to the current laboratory systems that may take from a couple of hours and up to a week to process samples.

*\*Surface-enhanced Raman Spectroscopy (SERS) is a technique that enhances Raman scattering of molecules embedded on a given surface by several orders of magnitude through the amplification of the electron cloud density around these molecules. Typical SERS signal enhancement factors (EF) are observed between  $10^6$  and  $10^{10}$  times, thus enabling a lower limit of detection and making the tests more sensitive.*

## 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 condensed interim consolidated financial statements for the six months ended January 31, 2024

### Selected quarterly information (in thousands of dollars except per share amounts)

Income statement	Q2 2024	Q1 2024	Q4 2023	Q3 2023	Q2 2023	Q1 2023	Q4 2022	Q3 2022
	\$	\$	\$	\$	\$	\$	\$	\$
Revenue	148	118	35	106	171	122	128	324
Cost of sales	(80)	(47)	15	(45)	(81)	(23)	(32)	(227)
Gross Profit	68	71	50	61	90	99	96	97
Operating expenses	(579)	(669)	(495)	(694)	(460)	(596)	(506)	(393)
Other expenses (gains)	(80)	(182)	(518)	43	(121)	(135)	(53)	(115)
Net earnings (loss) before tax	(591)	(780)	(963)	(590)	(491)	(632)	(463)	(411)
Balance sheet	Q2 2024	Q1 2024	Q4 2023	Q3 2023	Q2 2023	Q1 2023	Q4 2022	Q3 2022
	\$	\$	\$	\$	\$	\$	\$	\$
Current assets	2,614	2,682	1,692	1,816	1,658	1,658	1,658	1,874
Non-current assets	1,851	1,904	1,960	2,013	2,066	2,119	2,172	2,224
Total assets	4,465	4,586	3,652	3,829	3,724	3,777	3,830	4,098
Current liabilities	17,904	17,458	15,726	14,886	14,631	14,393	14,138	13,902
Non-current liabilities	2,642	2,940	2,957	3,012	2,572	2,372	2,048	2,089
Total liabilities	20,546	20,398	18,683	17,898	17,203	16,765	16,186	15,991
Total shareholders' deficiency	(16,081)	(15,812)	(15,031)	(14,069)	(13,479)	(12,988)	(12,356)	(11,893)
Total liabilities and equity	4,465	4,586	3,652	3,829	3,724	3,777	3,830	4,098

This quarterly information is unaudited but has been prepared on the same basis as any other annual consolidated financial statements. We discuss the factors that caused our results to vary over the past eight quarters throughout this MD&A. The main highlights are:

- The increase in revenue is due to increased service revenue related to continued research and development projects.
- The increase in operating expenses is a direct result of increased regulatory activities coupled with an increase in foreign exchange loss due to the strengthen of the US dollar and Swiss Franc.
- The increase in other expenses over the last several quarters is a result of increased interest in overdue account payable.

## Second quarter analysis

	<b>for the three months ended</b>		<b>Better (worse)</b>
	<b>31-Jan-24</b>	<b>31-Jan-23</b>	
<b>Product</b>			
Product sales	56,205	84,614	(28,409)
Product cost of sales	<u>(11,191)</u>	<u>(11,862)</u>	<u>671</u>
<b>Gross margin on product</b>	<u>45,014</u>	<u>72,752</u>	<u>(27,738)</u>
<b>Services</b>			
Service sale	92,491	85,924	6,567
Service cost of sales	<u>(69,368)</u>	<u>(68,739)</u>	<u>(629)</u>
<b>Gross margin on services</b>	<u>23,123</u>	<u>17,185</u>	<u>5,938</u>
<b>Operating expenses</b>			
Research and development	(76,357)	(106,359)	30,002
Sales and marketing	(85,480)	(4,730)	(80,750)
Other direct costs	(200,557)	(185,280)	(15,277)
General and administrative	<u>(216,980)</u>	<u>(163,377)</u>	<u>(53,603)</u>
<b>Total operating expenses</b>	<u>(579,374)</u>	<u>(459,746)</u>	<u>(119,628)</u>
<b>Operating loss</b>	<u>(511,237)</u>	<u>(369,809)</u>	<u>(141,428)</u>
<b>Non-operating income (expense)</b>			
Government assistance	143,088	-	143,088
Financing	<u>(222,640)</u>	<u>(120,699)</u>	<u>(101,941)</u>
<b>Total non-operating expense</b>	<u>(79,552)</u>	<u>(120,699)</u>	<u>41,147</u>
<b>Net and comprehensive loss</b>	<u>(590,789)</u>	<u>(490,508)</u>	<u>(100,281)</u>

### *Product revenue and gross margin*

The Company recorded revenue from product sales in the three months ended January 31, 2024, of \$56,205 as compared to \$84,614 for the same period last year. The Company expects these revenues to increase over the next financial quarters due to receipt of the latest FDA approval in December 2023. The change of the product sold in the United States had a transition period.

Gross profit on product sales for the three months ended January 31, 2024, of \$45,014 compared to \$72,752 for the same period in fiscal 2023. The gross margin is what the company would expect given the mix of products sold.

### *Service revenue and gross margin*

The Company recorded revenue from service sales in the three months ended January 31, 2024, of \$92,491 compared to \$85,924 for the same period in fiscal 2023. The service revenue is directly related to the company's Reveal G4 line.

### *Operating expenses*

Total operating expenses increased by \$119,628 from \$459,746 for the three months ended January 31, 2023, to \$579,374 for the three months ended January 31, 2024.

- Research and development expenses for the three months ended January 31, 2024, were \$76,357 compared to a \$106,359 for the same period in fiscal 2023. The decrease of approximately 28% was due to the completion of the development of the Company's latest product development.
- Sales and marketing expenses for the three months ended January 31, 2024, were \$85,480 compared to \$4,730 for the same period in fiscal 2023. The increase is related to increased sales and marketing activities as outlined in the Corporate Update in this MD&A.
- Other direct costs for the three months ended January 31, 2024, were \$200,557, compared to \$185,280 for the same period in fiscal 2023. Other direct costs increased by approximately 8% as the moved products from research and development into regulatory approval.
- General and administrative expenses were \$216,980 for the three months ended January 31, 2024, compared to \$163,377 for the same period in fiscal 2024. The increase of approximately 33% was due to increased foreign exchange loss due to the strengthen of the US dollar and Swiss Franc and increased professional fees. The management has been tasked by its board of directors is to maintain the lowest cash burn for non-essential expenses, however, foreign exchange fluctuations can only be mitigated in a limited capacity.

### *Non-operating expenses*

- Total financing expenses were \$222,640 in the three months ended January 31, 2024, compared to \$120,699 during the same period in fiscal year 2023. The increase of 85% in finance expenses is due to increased interest on accounts payable as well as the increased interest expense accrued. The finance expenses are offset by a government assistance in the amount of \$143,088 received in the three months ended January 31, 2024, compared to nil last year. This government assistance arises from the scientific and experimental research and development refund from the 2023 tax return.

## Year to date analysis

	for the six months ended		Better (worse)
	31-Jan-24	31-Jan-23	
<b>Product</b>			
Product sales	125,584	158,250	(32,666)
Product cost of sales	(25,844)	(22,644)	(3,200)
<b>Gross margin on product</b>	<u>99,740</u>	<u>135,606</u>	<u>(35,866)</u>
<b>Services</b>			
Service sale	140,974	133,058	7,916
Service cost of sales	(101,944)	(80,460)	(21,484)
<b>Gross margin on services</b>	<u>39,030</u>	<u>52,598</u>	<u>(13,568)</u>
<b>Operating expenses</b>			
Research and development	(176,844)	(295,274)	118,430
Sales and marketing	(155,907)	(15,901)	(140,006)
Other direct costs	(406,582)	(386,742)	(19,840)
General and administrative	(508,770)	(357,983)	(150,787)
<b>Total operating expenses</b>	<u>(1,248,103)</u>	<u>(1,055,900)</u>	<u>(192,203)</u>
<b>Operating loss</b>	<u>(1,109,333)</u>	<u>(867,696)</u>	<u>(241,637)</u>
<b>Non-operating income (expense)</b>			
Government assistance	143,088	-	143,088
Financing	(404,904)	(255,261)	(149,643)
<b>Total non-operating expense</b>	<u>(261,816)</u>	<u>(255,261)</u>	<u>(6,555)</u>
<b>Net and comprehensive loss</b>	<u>(1,371,149)</u>	<u>(1,122,957)</u>	<u>(248,192)</u>

### *Product revenue and gross margin*

The Company recorded revenue from product sales in the six months ended on January 31, 2024 of \$125,584 as compared to \$158,250 for the same period last year. Gross profit on product sales for the six months ended January 31, 2024 was \$99,740 compared to \$135,606 for the same period in 2023. The Company expects these revenues to increase over the next financial quarters due to receipt of the latest FDA approval in December 2023. The change of the product sold in the United States had a transition period.

### *Service revenue and gross margin*

The Company recorded revenue from service sales in the six months ended on January 31, 2024, of \$140,974 compared to \$133,058 for the same period in 2023. The increase was due to the continuation of product specific development work funded by third parties.

### *Operating expenses*

Total operating expenses increased by \$192,203 from \$1,055,900 for the six months ended on January 31, 2023, to \$1,248,103 for the six months ended on January 31, 2024.

## Management's Discussion & Analysis

For the six months ended January 31, 2024

- Research and development expenses for the six months ended on January 31, 2024, were \$176,844 compared to \$295,274 for the same period in 2023. The decrease of 40% in research and development expenses are due to the completion of the Company's Reveal® and Multiplo® products.
- Sales and marketing expenses for the six months ended on January 31, 2024, were \$155,907 compared to \$15,901 for the same period in 2023. The increase is related to increased sales and marketing activities in both the US and Europe market in anticipation of the approval of new products.
- Other direct costs for the six months ended January 31, 2024, were \$406,582, compared to \$386,742 for the same period in 2023. This increase of approximately 5% is due to increased regulatory fees as products move from research and development into the regulatory approval stage.
- General and administrative expenses were \$508,770 for the six months ended January 31, 2024, compared to \$357,983 for the same period in 2023. The increase is due to the increasing value of the United States dollar and the Swiss Franc compared to the Canadian dollar. The amount for General and administrative expenses for the six months are in line with the Company's overall costs.

### *Non-operating expenses*

- Total non-operating expenses were \$261,816 in the six months ended January 31, 2024, compared to \$255,261 during the same period in 2023. The small increase is due to the increased interest expense the company is paying on its debt by investors which are offset by the scientific and experimental research and development refund tax refund from the 2023 tax return.

### **Geographic information**

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

	for the three months ended		for the six months ended	
	31-Jan-24	31-Jan-23	31-Jan-24	31-Jan-24
	\$	\$	\$	\$
Product sales	56,205	84,614	125,584	158,250
Service sales	92,491	85,924	140,974	133,058
Total Revenue	148,696	170,538	266,558	291,308

	for the three months ended		for the six months ended	
	31-Jan-24	31-Jan-23	31-Jan-24	31-Jan-24
	\$	\$	\$	\$
North America	123,122	162,657	233,805	273,157
Europe	25,574	7,881	32,753	18,151
Total Revenue	148,696	170,538	266,558	291,308

### **Liquidity and capital resources**

### *Cash and working capital*

The Company had cash reserves of \$853,821 on January 31, 2024, compared to \$13,178 on July 31, 2023. The Company's net working capital position as of January 31, 2024 was a deficit of \$15.3 million compared to the July 31, 2023 working capital deficit of \$14.0 million. The Company has incurred operational losses and negative cash flows on a cumulative basis since inception. For the six months ended January 31, 2024, the Company incurred a net loss from operating activities of approximately \$1.1 million and cash outflows from operations of \$1.2 million, compared to a net loss from operations of \$0.9 million and cash outflows from operations of \$0.5 million for the same period in fiscal 2023. The following table is a list of commitments the Company has:

#### **For the six months ended January 31, 2024**

	<b>Total</b>	<b>Less than 1 year</b>	<b>1 to 3 years</b>	<b>4 to 5 years</b>	<b>After five years</b>
	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>	<b>\$</b>
Debt	6,995,155	6,109,442	885,713	-	-
Accounts payable and accrued liabilities	7,974,110	7,974,110	-	-	-
Lease liabilities	1,931,290	174,426	592,672	462,976	701,216
Advance from investors	2,923,239	2,923,239	-	-	-
Royalty provision	84,673	84,673	-	-	-
<b>Total debt</b>	<b>19,908,467</b>	<b>17,265,890</b>	<b>1,478,385</b>	<b>462,976</b>	<b>701,216</b>

### *Operating activities*

MedMira incurred cash outflows from operations of approximately \$1.2 million for the six months ended January 31, 2024, compared to cash outflows of \$0.5 million for the same period in fiscal 2023.

### *Financing activities*

Cash inflows from financing activities were \$2.1 million for the six months ended January 31, 2024, compared to cash inflows of \$0.6 million for the same period in fiscal 2023.

### **Debt**

As of January 31, 2024, the Company had loans payable with a carrying value of \$7.0 million compared to \$7.3 million at July 31, 2023. During the past 18 months, the Company was in negotiations with all of its debt holders to ensure realistic debt repayment plans, which shall enable the Company to use its working capital for its growth and ensure its future stability. As these negotiations are ongoing, the Company must record these as in default until final agreements have been signed. All the loans are currently in default due to non-payment of principal and interest and therefore show as a current liability on the balance sheet.

Further discussion on liquidity and capital resources can be found in this document in the Liquidity Risk section, Risk and Uncertainties section of this document and in Notes 2 and 8 of the Company's consolidated financial statements for the three months ended January 31, 2024.

### **Equity/Shares**

The Company is authorized to issue an unlimited number of common shares without par value. The number of issued and outstanding common shares on January 31, 2024 was 701,730,591. During the six months ended January 31, 2024, the company converted debt totalling \$321,370 into 4,284,931 common shares. 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 January 31, 2024.

### **Off balance sheet arrangements**

The Company was not party to any off balance sheet arrangements as of January 31, 2024.

### **Capital Management and Financial Risks**

#### *Liquidity risk*

The accompanying consolidated financial statements have been prepared on the basis of IFRS applicable to a going-concern, which contemplates the realization of assets and liquidation of liabilities during the normal course of operations. However, certain adverse conditions and events cast significant doubt upon the validity of this assumption.

The Company has incurred losses and negative cash flows from operations on a cumulative basis since inception. For the six months ended January 31, 2024, the Company realized a net loss of \$1.4 million (January 31, 2023 – net loss of \$1.1 million), consisting of a net loss from operations of \$1.1 million (January 31, 2023 – net loss of \$0.9 million), and other non-operating losses of \$0.3 million (January 31, 2023 - \$0.2 million). Negative cash outflows from operations were \$1.2 million (January 31, 2023 – \$0.5 million). As of January 31, 2024, the Company had an accumulated deficit of \$99.3 million (July 31, 2023 - \$98.0 million) and a negative working capital position of \$15.3 million (July 31, 2023 - \$14.0 million). In addition, as of January 31, 2024, \$6.1 million of debt was in default. The Company currently has insufficient cash to fund its operations for the next 12 months. In addition to its ongoing working capital requirements, the Company must secure sufficient funding for its research and development programs for existing commitments, including its current portion of debt of approximately \$6.1 million. These material uncertainties may cast significant doubt about the Company's ability to continue as a going concern.

The Company's objectives in managing capital are to ensure it can meet its ongoing working capital requirements. The Company must secure sufficient capital to support its capital requirements for research and development programs, existing commitments, including its current portion of debt of approximately \$6.1 million, as well as growth opportunities.

Management dedicates significant time to pursuing investment alternatives that will fund the Company's operations and growth opportunities so it can continue as a going concern. Debt arrangements were also ongoing with the Company's major shareholder and other debt holders. After the close of the first quarter of fiscal year 2024, the Company, has generated additional revenues from product sales and service revenue which support the Company's on-going operating costs and provide funding for its product development activities. Management continues to work closely with its main investor to support any additional cash requirements if needed, nevertheless there is no assurance that this initiative would be successful.

The Company is subject to risks associated with early stage companies, including but not limited to, dependence on key individuals, competition from substitute services and larger companies, and the requirement for the continued successful development and marketing of its products and services. The Company's ability to continue as a going-concern is dependent upon its ability to generate positive cash flow from operations and secure additional financing and the continued support of its lenders and shareholders. These financial statements do not reflect the adjustments to carrying values of assets and liabilities and the reported expenses and statement of financial position classifications that would be necessary were the going-concern assumption not appropriate. These adjustments could be material.

### *Credit risk*

The Company exposed to credit risk in relation to its trade accounts receivable. To mitigate such risk, the Company continuously monitors the financial condition of its customers and reviews the credit history or worthiness of each new customer. The Company mitigates this risk by requiring a 100% down payment for any orders received by new clients at the time of purchase. The Company establishes an allowance for doubtful accounts based on specific credit risk of its customers by examining such factors as the number of overdue days of the customers' balance outstanding as well as the customers' collection history. Since 89% of the Company's sales are with four large international companies with which the Company has distribution agreements since over 10 years, there is no significant concentration of credit risk.

Trade and other receivables include amounts that are past due as of January 31, 2024, for which the Company has not recognized an allowance for doubtful accounts because there has not been a significant change in the credit quality of the customer and the amounts are still considered recoverable.

### *Currency risk*

MedMira receives most of its revenues in foreign currencies and incurs expenses in U.S. and Canadian currencies. As a result, the Company is subject to uncertainty as foreign exchange rates fluctuate. The exchange fluctuations from year to year have accounted for a significant portion of the Company's exchange gain and loss. Most sales are 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 U.S and CHF denominated cash, U.S. accounts receivable, US and CHF denominated accounts payable and U.S. and CHF denominated promissory notes.

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

### *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 with related parties during the six months ended January 31, 2024:

- An advance from an investor of \$669,850 was received from a shareholder (July 31, 2023 - nil)

The following balances with related parties were outstanding on January 31, 2024:

- Salaries and benefits totalling \$1,379,469 were due to the CEO and CFO (July 31, 2023 - \$1,232,784).
- A long-term loan totalling \$5,990 (July 31, 2023 - \$5,824) and accrued interest of \$665 (2023 - \$500) was due to the Chief Financial Officer (July 31, 2023- \$5,824).
- A royalty provision was owed to MedMira Holding AG of \$84,673 (July 31, 2023 - \$84,673).
- Short term loans totalling \$162,285 (July 31, 2023 - \$157,794) and accrued interest of \$34,668 (2023 - 29,731) were owed to one officer.
- Long term loans totalling \$482,856 (July 31, 2023 - \$469,495) and accrued interest of \$25,344 (2023 - 12,809) were owed to a shareholder.
- A long-term loan totalling \$155,760 (July 31, 2023 - \$151,450) and accrued interest of \$6,444 (2023 - \$2,488) was owed to a member of the board of directors.
- An advance from an investor totaling \$669,850 (July 31, 2023 - nil) and accrued interest of \$16,609 (July 31, 2023 - nil) was owed to a shareholder.

- Expenses in the amount of \$16,921 (July 31, 2023 - \$16,454) were owed to an officer.

### Compensation summary

#### A) Officers for Q2 FY2024

Name and Principal Position	Paid Compensation (\$)	Accrued Compensation Current year (\$)	Share- and Option-based Awards* (\$)	All other compensation (\$)	Total Compensation current year (\$)	Paid Compensation related to previous fiscal years (\$)	Accrued Compensation related to previous fiscal years (\$)
Hermes Chan CEO	16,154	10,769	-	-	26,923	25,897	568,808
Markus Meile CFO	-	16,154	-	-	16,154	-	769,299

<sup>1</sup> All other compensation includes pension fund contributions and/or bonuses paid out.

\*The Company makes certain estimates and assumptions when calculating the fair value of option-based awards. The Company uses an option-pricing model, which includes significant assumptions including estimates of the expected volatility, expected life, expected dividend rate and expected risk-free rate of return. Changes in these assumptions may result in a material change to the amounts recorded for the issuance of stock options.

#### B) Directors for Q2 FY2024

Name and Principal Position	Paid Compensation (\$)	Accrued Compensation Current year (\$)	Share- and Option-based Awards* (\$)	Total Compensation current year (\$)	Paid Compensation related to previous fiscal years (\$)	Accrued Compensation related to previous fiscal years (\$)
Hermes Chan Member of the Audit Committee and Nomination and Compensation Committee	-	-	-	-	-	-
Steven Cummings, Director, Member of the Audit and Nomination and Compensation Committee	-	-	-	-	-	-
Jianhe Mao, Director, Member of the Audit and Nomination and Compensation Committee	-	-	-	-	-	-

Thomas Bergmann, Director, Member of the Audit Committee and Nomination and Compensation Committee	-	-	-	-	-	-
Pascale Nini, Director, Member of the Audit Committee and Nomination and Compensation Committee	-	-	-	-	-	-

\*The Company makes certain estimates and assumptions when calculating the fair value of option-based awards. The Company uses an option pricing model which includes significant assumptions including estimates of the expected volatility, expected life, expected dividend rate and expected risk-free rate of return. Changes in these assumptions may result in a material change to the amount recorded for the issuance of stock options.

**Subsequent events**

The Company has received \$3,000,000 in advance payments.

In addition, the Company is finalizing debt conversions with some of its debt holders in order to significantly decrease its liabilities.

**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 on January 31, 2024.

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 condensed interim consolidated

financial statements of MedMira for January 31, 2024, 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 facility's 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 FDA, the CFDA, CE Mark 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 CFDA 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, dependent 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 United States, a relationship has been established with a number of distributors to support the logistics and distribution of the Company's products. The Company will rely on the joint efforts of Medline Industries and distributors Cardinal Health, a Fortune 100 company, and VWR International to distribute MedMira's product line.

Outside the United States, 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.

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, CE, CFDA 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 attempts 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 United States, Canada, China, and other foreign countries relating to various aspects of its rapid diagnostic platform, processes, reagents, and equipment. Although it is management's belief 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.