Corporate update

In the second financial quarter of FY2022, MedMira continued its strategic plan to focus its own product portfolio on the two fastest growing disease segments in the IVD rapid test market. Furthermore, the Company continued its work with public and private partners to develop new potential tests based on its Rapid Vertical Flow (RVF) Technology® platform.

Sexually Transmitted Infections (STI)

MedMira has positioned itself with its HIV, HCV (Hepatitis C), TP (Syphilis) products in these three major and fastest growing STI segments. The growth rate for each of the markets are at a CAGR between 3 – 6 %, which highlights the significant potential for MedMira's high quality rapid testing solutions. In addition, recent steps taken by regulators to prioritise testing alternatives such as rapid testing for these diseases further outline the high demand MedMira's products.

COVID-19

Currently there is a growing trend to shift SARS-CoV-2 from a pandemic to an endemic situation. Whereas this change may be more politically and economically motivated, it contrasts with the scientific data which show an increasing prevalence rate. The need for testing may not be a requirement or an obligation by public institutions, however, it will steadily move towards home testing and self-protection. Decreasing or ending public requirements to protect individuals from SARS-CoV-2 may result in further large-scale outbreaks over time.

In a press release issued by the US National Institute of Health (NIH) on March 31, 2022 stated "Dr. Fauci and his colleagues write that achieving classical herd immunity against SARS-CoV-2 is unlikely, due to a combination of factors that include features of the virus as well as current societal dynamics. These include the virus' ability to continually mutate to new variants; asymptomatic virus transmission, which complicates public health control strategies; the inability of prior infection or vaccination to provide durable protection against reinfection; suboptimal vaccination coverage; and adherence to non-pharmacologic interventions." Living with COVID is best considered not as reaching a numerical threshold of immunity, but as optimizing population protection without prohibitive restrictions on our daily lives, the authors conclude.

Notwithstanding the terminology or public perception of the severeness of SARS-CoV-2 moving forward, testing is and continuous to be essential for health care providers and individuals. MedMira's four COVID-19 products provide a testing solution to screen (antigen testing) for acute infections, monitor protection levels (antibody testing) and provide an answer for end-users Covid-19 or Flu. Screen, monitor – know.

Regulatory update United States

In January 2022, the U.S. FDA announced the introduction of the traditional approval under the classification of the De Novo/510(k) Classification Request process. This is a pathway for manufacturers of novel medical devices seeking marketing authorization as a Class I or Class II device. The advantages of the De Novo Classification Request for new devices include expeditious review times and a fixed classification decision lending to more certainty within the device's regulatory lifespan. While the EUA process is on-going, the Company has prepared the necessary De Novo 510(k) pre-submissions for its REVEALCOVID-19® and VYRA™ product lines. Due to further considerations, the process has not yet been fully implemented for rapid testing system and the Company is awaiting the final guideline in order to commence with its application. The first and only De Novo 510(k) clearance of molecular SARS_CoV-2 test was given to the BioFire Respiratory Panel 2.1 on March 17, 2021. FDA has not yet cleared any subsequent 510 (k) for molecular SARS-CoV-2 diagnostic test since. While the De Novo 510(k) regulatory process for rapid test is still pending, the Company has had communications with FDA on the current pre-submissions for SARS-CoV-2 related product lines.

During the second financial quarter of 2022, the Company filed its pre-submission for the De Novo/510(k) Classification Request for its Reveal® Hepatitis C (HCV) Rapid Antibody Test and received the letter of acknowledgment from FDA (CDRH). Our clinical development team has been working closely with the clinical research organization (CRO) in clinical site selection in US while FDA is reviewing the submitted clinical trial protocol. We anticipate the clinical trial may take place in early summer this year.

MedMira's Reveal® G4 HIV test, was previously FDA/PMA approved, has started the clinical trials required to complete its last phase of regulatory work to obtain the FDA CLIA-waived listing. This new claim allows the Company to access the over USD$ 350 million annual market in the United States which includes physician-office-lab (POL) facilities, clinics, and other community healthcare providers.

Regulatory Update Europe

Subsequent to the end of the second financial quarter of FY2022, the Company received the CE mark for its REVEALCOVID-19® PLUS Total Antibody Test and commenced its commercialization efforts in all markets accepting the CE mark. Sales generated from this product will contribute towards the Company's overall sales within the coming months. Furthermore, the Company is anticipating at least two additional CE marks for its other COVID-19 products within the coming two months. In addition, MedMira will commence on at least one CE mark application for a Sexually Transmitted Disease test (to be announced at a later stage) prior to the 26th of May 2022.

Changes to the regulatory framework in the CE marketplace

The European Medical Device landscape is in the process of dramatic change, attributable to the upcoming introduction of Regulation (EU) 2017/746, better known as the IVDR (In-Vitro Diagnostic Regulation). The IVDR will replace the existing medical device regulation, IVDD, and will cover all EU member states.

The additional considerations introduced by the IVDR apply to all manufacturers seeking CE marking for new medical devices and existing devices previously certified under the IVDD (i.e., legacy devices). These considerations include more rigorous risk classifications, quality management system requirements, and performance evaluation standards. Approvals under the IVDR will require more time and effort from both manufacturers and Notified Bodies, who are now responsible for certifying 80% of prospective medical devices (compared to 20% under the IVDD).
Legacy devices will be subject to gap analysis after May 26, 2022, when they must meet the strict requirements of the IVDR on-top of their existing conformity to the IVDD. Many self-certified devices, however, will need to undergo a complete IVDR conformity assessment and certification through a Notified Body. The deadline for this approval depends on the new IVDR risk classification of formerly self-certified devices and will require a major commitment from manufacturers.

As a result, higher entry barriers will be established in the CE market place and a more stringent focus will be placed on the quality of components, manufacturing processes and standards, and performance quality of products. With this change, CE approval will be aligned closer to the strict regulatory framework as applied by the U.S. FDA. This provides a unique opportunity for manufacturers such as MedMira which have built over the years high quality manufacturing processes and achieved the necessary accreditations. The Company's focus on the quality of its products and acquisition of supporting evidence will be key to its future success in the CE market place. It is management's view that these changes will significantly impact the competitive landscape and the pricing model in favour of MedMira.

Regulatory Update Canada

A partnership with REACH Nexus (www.reachnexus.ca) at the MAP Centre for Urban Health Solutions (www.maphealth.ca) was entered into for the sponsorship of the clinical trials in Canada was agreed. The partnership will allow the Company to perform a clinical trial evaluation at 10 testing sites and with the data generated, a Health Canada approval can be achieved. At this stage, MedMira's Reveal® TP (Syphilis) Rapid Test

would be only product available on the Canadian market. Subsequent to the end of the second financial quarter FY2022, MedMira filled its ITA which is currently under review by Health Canada. After the approval, the Company is able to commence with the clinical trials.

COVID-19: The third (3) Interim Order process has been released by Health Canada as of February 21, 2022 relating to COVID-19 products which has allowed MedMira to discuss pending and future applications. "*Whereas the Minister of Health believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment. Therefore, the Minister of Health, pursuant to subsection 30.1(1) of the Food and Drugs Act, makes the annexed Interim Order No. 3 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19."* Ottawa, February 21, 2022, Jean-Yves Duclos, Minister of Health.

As a result of these discussions the Company was informed that the priority is set at SARS-CoV-2 antigen home tests and a more efficient process has been established to decrease the review time; increase communication; and allow Canadian manufacturers to support the government's increasing demand for SARS-CoV-2 antigen tests. While antibody testing is not yet a priority, the Company REVEALCOVID-19® Total Antibody Test application is still pending. Currently the focus is set on antigen testing in anticipation of the next wave that may cause higher infections within Canada. The Company welcomes these regulatory new processes and can move forward with its application for VYRA™ Antigen Tests. Data received from independent evaluations carried out in recent month in both Canada and Germany demonstrated accuracy close to 100% in identify acute SARS-CoV-2 infected patients.

Sales update

In Q2 FY2022, the Company recorded higher sales of its non-COVID-19 products in comparison to the last financial quarter which was in line with management's expectations. Sales for its COVID-19 products were significant lower in comparison to the same financial quarter last year which was mainly due to the temporary halt in sales in the US for its REVEALCOVID-19® Antibody Test until the EUA has been granted. Subsequent to Q2 FY2022 and the CE mark of REVEALCOVID-19® PLUS Antibody Test, MedMira will generated higher sales for this product line. Furthermore, the CE mark of MedMira's Reveal® TP (Syphilis) Rapid Test received in March 2022, will further enhance its overall sales in the coming financial quarters. The increasing prevalence rates of Syphilis globally and the support of various governments in Europe to offer free or subsidised testing provides a substantial sales opportunity for MedMira's easy-to-use and highly sensitive Syphilis test.

Financial update

The Company's Finance team continued its fiscal constraints to maintain its low fixed costs with the aim to achieve breakeven and subsequent profitability within a short period of time. During FY2022, the Company continued its efforts to renegotiate its debt and achieved a forbearance agreement with MedMira's largest debt holder which allows the Company to defer principal and interest payments for 12 months. This may be extended further depending on the growth of the Company. In Q2 FY2022, MedMira completed a financial package agreement with its largest shareholders. This provided the Company with additional cash to execute its clinical trials (G4 HIV CLIA-waived Rapid Test), to continue its operations and to further invest into the manufacturing facility in Halifax. Furthermore, MedMira's largest shareholders have converted $3,564,435.92 debt into shares in order to support the Company in its efforts to reduce its debts and support its going concern.