#### MED BIOGENE INC.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

#### INTRODUCTION

The following management discussion and analysis of the financial condition and results of operations ("MD&A") of Med BioGene Inc. (the "Company" or "MBI") has been prepared by management, in accordance with the requirements of National Instrument of 51-102 as of May 27, 2019 and should be read in conjunction with the unaudited condensed consolidated interim financial statements for the three-month period ended March 31, 2019 and the related notes contained therein which have been prepared under International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). The following should also be read in conjunction with the annual audited consolidated financial statements and the related MD&A for the year ended December 31, 2018, and all other disclosure documents of the Company. The information provided in this document is not intended to be a comprehensive review of all matters and developments concerning the Company. Additional information relevant to the Company's activities can be found on SEDAR at <a href="www.sedar.com">www.sedar.com</a> and the Company's website at <a href="www.medbiogene.com">www.medbiogene.com</a>.

All financial information in this MD&A related to 2019 and 2018 has been prepared in accordance with IFRS and all dollar amounts are quoted in US dollars, the reporting currency of the Company, unless noted otherwise.

#### FORWARD-LOOKING INFORMATION

Certain information in this MD&A contains forward-looking information and statements ("forwardlooking information") of MBI under applicable Canadian and United States legislation. Words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking information, although not all forward-looking information contains these identifying words. Forward looking information includes, but is not limited to, that with respect to the timing, completion and/or results of clinical trials or studies, the timing for commercialization of any products, future profits, future product revenues, future shareholder value, future operations and plans, the completion and use of proceeds from transactions or financings and the prospects for negotiating partnerships or collaborations and their timing. This forward-looking information is only a prediction based upon MBI's current expectations, and actual events or results may differ materially. MBI may not actually achieve the plans, intentions or expectations disclosed in its forward-looking information. Forward-looking information is subject to known and unknown risks and uncertainties and is based upon uncertain assumptions that could cause a MBI's actual results and the timing of events to differ materially from those anticipated in such forward-looking information. You are cautioned not to place undue reliance on this forward-looking information, which speak only as of the date of this MD&A. MBI's forward-looking information does not reflect the potential impact of any future partnerships, collaborations, acquisitions, mergers, dispositions, joint ventures or investments that MBI may make. All forward-looking information herein is qualified in its entirety by this cautionary statement and MBI undertakes no obligation to revise or update any such forward-looking information as a result of new information, future events or otherwise after the date of this MD&A, other than as required by applicable law. Certain information included in this MD&A in respect of Helomics<sup>TM</sup> (formerly "Precision Therapeutics Inc.") and the prior relationship with MBI concerning its scientific, clinical and or commercialization efforts and expectations have been provided to MBI by Helomics<sup>TM</sup>. MBI may not have been able to confirm the accuracy of such information and you should not place undue reliance on any such information, including any information regarding Helomics<sup>TM</sup> that may constitute forwardlooking information. A redacted copy of the Commercialization Agreement and Termination Agreement between MBI and Helomics<sup>TM</sup> may be found at www.sedar.com. Each trademark, trade name or service

mark of any entity appearing in this MD&A belongs to its holder.

#### GOING CONCERN UNCERTAINTY

It is believed that MBI's ability to continue as a going concern and achieve its business objectives is dependent upon obtaining significant additional financing. On November 28, 2016, MBI announced a termination and settlement of the prior commercialization and licensing agreement (as amended, the "Commercialization Agreement") with Helomics<sup>TM</sup> Corporation. This terminates the original licensing agreement put in place in 2011 by prior MBI management and relieves MBI of all the encumbrances associated with this agreement.

Since that time, MBI has acted to secure new commercial agreements. As of this writing, no new agreement has been executed, and MBI remains committed to exploring all possible options. While the termination and settlement of the prior Helomics<sup>TM</sup> agreement relieved MBI of any and all indebtedness and other obligations, it provided only limited actual cash to MBI.

As a result MBI continues to operate in as lean a manner as possible to conserve cash reserves while exploring other commercialization options. The Company needs to find another licensing partner for its intellectual property in order to maintain operations. Management strongly believes the existing clinical and utility test data for the test is compelling and is pursuing all available options to establish a new licensing partner. Management's intention is to implement a much simpler licensing agreement structure than was previously in place, with stronger mechanisms to ensure a royalty stream begins sooner and is less cluttered by encumbrances and other setoffs. Such a relationship will also depend on the willingness of the new licensing partner to entertain such terms in the final agreement.

If MBI needs to raise additional funds through the sale of equity or debt securities or the merger or sale of MBI, the sale of such additional equity and debt securities may result in dilution to MBI shareholders, or it may not be available in amounts or on terms acceptable to MBI. If additional capital is required and not obtained, MBI may be forced to cease operations.

#### **BUSINESS**

MBI is a life science company focused on commercializing the Signature and finding a licensee to it and for GeneFx $\otimes$  Lung, a prognostic genomic-based test for non-small-cell lung cancer ("NSCLC") developed by Helomics $^{TM}$  and licensed to MBI under the Settlement Agreement.

# The Signature and GeneFx® Lung

Early-stage NSCLC patients are treated primarily by surgical removal of their tumors. Recent clinical trials have established that adjuvant chemotherapy, administered after tumor removal, significantly improves the survival of stage II patients, but does not significantly improve the survival of stage I patients. As a result, the American Society of Clinical Oncology and National Comprehensive Cancer Network recommend adjuvant chemotherapy for stage II patients but not for stage I patients.

Thirty to fifty-five percent of stage I and II patients die as a result of their disease, implying that patients diagnosed within the same stage of disease can have markedly different treatment responses and survival rates. Currently, tumor stage (determined by the size and location of the tumor and lymph node involvement) remains the strongest predictor of survival, but it fails to account for this difference in patient outcomes. The Signature and GeneFx® Lung is expected to help address this critical issue.

As published in the Journal of Clinical Oncology, the fifteen-gene Signature of GeneFx® Lung was

developed using five-year outcome data from untreated early-stage NSCLC patients from the National Cancer Institute of Canada Clinical Trials Group JBR.10 trial. In this study, patients classified by the Signature as higher risk benefited from adjuvant chemotherapy, and those classified as lower risk did not benefit, and may have experienced a detrimental effect, from adjuvant chemotherapy. The Signature was subsequently validated in predicting patient mortality in four independent studies involving data from tumor specimens totaling 676 untreated early-stage NSCLC patients.

This study was led by MBI's collaborators, Drs. Ming-Sound Tsao, Frances A. Shepherd and Igor Jurisica, at the Princess Margaret Cancer Center, University Health Network ("UHN") in Toronto. Other centers involved in the study included: University of Toronto; National Cancer Institute of Canada Clinical Trials Group and Queen's University; Center for Cancer Genome Discovery, Dana-Farber Cancer Institute; Broad Institute of Massachusetts Institute of Technology; Harvard University; Cleveland Clinic; and the Max Planck Institute for Neurological Research with Klaus-Joachim-Zülch Laboratories of the Max Planck Society and the Medical Faculty of the University of Köln.

On June 1, 2013, Helomics<sup>TM</sup> presented data regarding GeneFx® Lung at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois. The presentation was titled "Performance of a Prognostic Genomic Signature for Early-Stage NSCLC in Matched Fresh Frozen and RNA-Stabilized Tissue" and detailed the successful completion of the previously announced clinical studies to validate the use of GeneFx® Lung with tissue preserved by RNAlater®, a molecular fixative.

RNAlater® eliminates the need to flash-freeze specimens and to keep specimens frozen throughout storage and transport, a process that is cumbersome and costly and limits test adoption as many laboratories are not equipped to work with frozen specimens. It also eliminates the need for preserving tissue in formalin, which is known to cross-link and degrade the nucleic acids rendering them less suitable for specific downstream molecular applications.

This study was undertaken by Helomics<sup>TM</sup>, Almac Diagnostics Ltd. of Craigavon, Northern Ireland and Princess Margaret Cancer Center and UHN.

In March 2014, MBI announced the publication in the *Journal of Thoracic Oncology* of data demonstrating a second, independent validation of the fifteen-gene Signature of GeneFx® Lung entitled "Validation of a Histology-Independent Prognostic Gene Signature for Early-Stage, Non-Small-Cell Lung Cancer Including Stage IA Patients." The study validated in a prospective and blinded manner the prognostic accuracy of the GeneFx® Lung signature in an independent cohort of 181 early-stage (I and II) non-small-cell lung cancer (NSCLC) tumor specimens in different histologic subtypes.

The study was led by Drs. Ming-Sound Tsao, Frances A. Shepherd and Sandy D. Der at the Princess Margaret Cancer Centre, UHN, and included Dr. Igor Jurisica, Jenna Sykes, Melania Pintilie, Dr. Chang-Qi Zhu, Dr. Dan Strumpf and Ni Liu.

#### Commercialization of GeneFx® Lung

From 2011-2016, MBI had a relationship with Helomics<sup>TM</sup> (formerly Precision Therapeutics Inc.) which was intended to secure the commercialization of the MBI Signature and secure a royalty stream back to MBI. For various reasons that were not anticipated by MBI, and ultimately because of a change in strategic focus for Helomics<sup>TM</sup>, commercialization was never achieved, and MBI sought to recover its full unencumbered intellectual property rights via the termination and settlement agreement in November 2016.

As part of that agreement, MBI retained the right to pursue new licensees of the intellectual property in two forms: the first is the 'origin' IP, in the same form PTI/Helomics<sup>TM</sup> originally licensed it, and the second is the 'improved' IP which benefits from the lab and clinical work performed by Helomics<sup>TM</sup> during the term of the commercialization agreement.

These improvements include making use of Helomics<sup>TM</sup> CLIA-approved facility for processing samples, and capturing samples via RNAlater instead of as flash-frozen tissue.

The long-term commercial success of GeneFx® Lung will depend largely upon the extent to which government payors, such as Medicare and Medicaid, and other third-party payors reimburse the test. In the United States, payors generally require evidence of both analytical and clinical validity (i.e. reliability of test results associated with the target disease) as well as clinical utility (i.e. whether the test results affect actual clinical decision-making and, possibly, improve patient outcomes) before reimbursing for a molecular diagnostic test.

MBI believes that it has sufficient evidence of the analytical and clinical validity of GeneFx® Lung from peer-reviewed publications that demonstrate the prognostic power of the test.

The evidentiary requirements of payors in the United States relating to the clinical utility of high-value molecular diagnostic tests, which includes GeneFx® Lung, has varied over the last couple of years as among the numerous Medicare contract administrators who make coverage determinations within their jurisdictions, and as among other third-party payors. Also, specific payors have recently declined coverage of some molecular diagnostic tests citing a lack of evidence of clinical utility in the submissions.

# Collaboration with University Health Network

GeneFx® Lung was developed in collaboration with a team of internationally acclaimed researchers and physicians at Princess Margaret Cancer Center, UHN in Toronto. The team is led by Dr. Frances A. Shepherd, holder of the Scott Taylor Chair in Lung Cancer Research and the Past-Chair of the National Cancer Institute of Canada Clinical Trials Group Lung Cancer Site, and Dr. Ming-Sound Tsao, holder of the M. Qasim Choksi Chair in Lung Cancer Translational Research. Drs. Shepherd and Tsao are Professors at the University of Toronto and have in total authored more than 500 articles in peer reviewed journals.

Princess Margaret Cancer Center, a research hospital of the University of Toronto, has achieved an international reputation as a global leader in the fight against cancer and is considered one of the top comprehensive cancer treatment and research centers in the world. Princess Margaret Cancer Center, together with its research institute, the Ontario Cancer Institute, is a member of the University Health Network, which also includes the Toronto General Hospital and the Toronto Western Hospital. Princess Margaret Cancer Center is the only facility in Canada devoted exclusively to cancer research, treatment and education.

On November 28, 2016, the Company and Helomics<sup>™</sup> signed a settlement agreement which terminated the Commercialization Agreement dated April 15, 2011. Helomics<sup>™</sup> paid a lumpsum amount to the Company as a part of the settlement agreement which has been included as other income in the statement of comprehensive income (loss) for the year ended December 31, 2016.

#### RESULTS OF OPERATIONS

#### For the three months ended March 31, 2019 and 2018

Including certain expenses accrued but not incurred, as further described below, MBI recorded a loss of \$16,857 (\$0.00 per share) for the three months ended March 31, 2019 compared to a loss of \$13,237 (\$0.00 per share) for the three months ended March 31, 2018. The Company did not generate any revenue during the periods ended March 31, 2019 and 2018. The results are consistent with management's expectations for the periods.

# **Expenses**

General and administrative expenses consist of consulting fees, public company costs, facilities and office operations expenses, and professional fees.

Actual general and administrative expenses were \$16,857 for the three months ended March 31, 2019 compared to \$13,237 for the three months ended March 31, 2018. The increase from the previous period is primarily attributable to the increase in consulting and professional fees.

A summary of general and administrative expenses follows:

	Т	Three months ended March 31,		
		2019		2018
Facilities and operations	\$	2,594	\$	3,652
Professional fees		7,165		3,234
Public company costs		4,602		6,351
Consulting fees		2,496		-
		16,857		13,237

MBI does not utilize derivative instruments. While MBI does incur expenses denominated in U.S. dollars, MBI purchases foreign currency as required on the spot market. At present, management believes that the timing and size of such U.S. dollar transactions does not warrant active hedging; however, as the business develops in the future, some limited hedging activity may be undertaken.

MBI invests its cash reserves in liquid and highly secure investments. MBI does not hold any investments in asset backed commercial paper. Presently all of MBI's cash reserves are held on deposit with a major Canadian chartered bank. MBI does not guarantee any third party obligations and has not entered into any off-balance sheet arrangements.

# Other comprehensive income (loss)

Other comprehensive income (loss) results from the foreign exchange translation adjustments in MBI's condensed consolidated interim financial statements resulting from exchange rate differences between its functional currency, which is Canadian dollars, and its reporting currency, which is U.S. dollars.

## SUMMARY OF QUARTERLY RESULTS

# FOR THE THREE MONTHS ENDED:

	I	March 31, 2019	Dece	ember 31, 2018	Septo	ember 30, 2018	June 30, 2018
Revenue	\$	-	\$	_	\$	_	\$ _
Total expenses		16,857		9,201		7,792	24,387
Net loss		(16,857)		(9,201)		(7,792)	(24,387)
Total assets		9,883		3,465		5,575	7,464
Net income (loss) per share		(0.00)		(0.00)		(0.00)	(0.00)

	]	March 31, 2018	Dec	ember 31, 2017	Sept	ember 30, 2017	June 30, 2017
Revenue	\$	_	\$	_	\$	_	\$ -
Total expenses		13,237		28,471		11,068	23,501
Net loss		(13,237)		(28,471)		(11,068)	(23,501)
Total assets		9,493		1,376		6,083	16,540
Net income (loss) per share		(0.00)		(0.00)		(0.00)	(0.00)

#### CONTRACTUAL OBLIGATIONS

In April 2008 and February 2009, MBI entered into development and license agreements with UHN providing MBI with, among other things, exclusive world-wide rights to further develop and commercialize certain intellectual property underlying GeneFx® Lung. Under these agreements, MBI and UHN collaborated in certain activities related to the development and validation of GeneFx® Lung and associated data analysis and in the collection of patient specimens to be used in such activities. The research and development expense for this project incurred since inception through to the current period is approximately \$677,823. MBI is obligated to provide UHN with up to \$829,222 in research funding and milestone payments (approximately 90% of which relate to launch and post-launch commercialization milestone payments) along with royalties based on revenues from GeneFx® Lung.

MBI has \$163,264 (2018 - \$137,282) in accounts payable, accrued liabilities and due to related parties which are due to suppliers and service providers in the normal course of business. Such amounts include certain payments due and accruals made concerning UHN under MBI's license and development agreement with them, as discussed above. In April, 2011, MBI announced the closing of the Commercialization Agreement with Helomics<sup>TM</sup>. The Commercialization Agreement provided to Helomics™ exclusive global rights to develop and commercialize GeneFx® Lung. Under the terms of the Commercialization Agreement, Helomics<sup>TM</sup> paid to MBI within 120 days of closing license fees and research reimbursement of \$2,292,589, half of which is credited against future royalties that may be owed to MBI by Helomics<sup>TM</sup>. In addition, MBI was eligible to receive from Helomics<sup>TM</sup> up to \$1.0 million in the following milestone payments, all of which are credited against future royalties that may be owed to MBI by Helomics<sup>TM</sup>: following the commercial launch of GeneFx® Lung, amounts totaling \$500,000 and, following the achievement of \$5 million in net revenues from GeneFx® Lung, amounts totaling \$500,000. MBI would receive royalty payments based on a percentage in the high single digits of Helomics<sup>TM</sup>'s future net revenues associated with the commercialization of GeneFx® Lung or any other products incorporating MBI's technology, which amounts are subject to MBI's obligation to pay to UHN royalties of a percentage in the high teens of the actual amounts received by MBI pursuant to the

sublicensing of technology licensed by MBI from UHN. Helomics<sup>TM</sup> is responsible for all future costs associated with the development and commercialization of GeneFx® Lung. Helomics<sup>TM</sup> is also responsible for paying all future payments to UHN under MBI's license agreements with UHN (other than certain amounts owed by MBI to UHN as sublicensing royalties of which \$222,816 was paid during the year ended December 31, 2011).

On November 28, 2016, the Company and Helomics<sup>TM</sup> signed a settlement agreement which terminated the Commercialization Agreement dated April 15, 2011. Helomics<sup>TM</sup> paid a lumpsum amount to the Company as a part of the settlement agreement which has been included as other income in the statement of comprehensive income (loss) for the year ended December 31, 2016. All other debts, setoffs, and other residual obligations from MBI back to Helomics<sup>TM</sup> were waived in full as a result of the settlement agreement.

#### RELATED PARTY TRANSACTIONS

During the period ended March 31, 2019, the Company:

- (i) Incurred \$2,257 (2018 \$2,372) for accounting fees to an officer of the Company;
- (ii) Incurred \$4,476 (2018 \$4,838) for accounting fees to a firm where a director of the Company is a partner.

Related party transactions are reflected as part of general and administrative expense. Amounts owing to these related parties (including former management and directors of the Company) as at March 31, 2019 were \$6,948 (December 31, 2018 - \$6,807). These amounts are non-interest bearing and due on demand.

# RECENTLY ADOPTED ACCOUNTING POLICIES

IFRS 16, *Leases* ("IFRS 16") – IFRS 16 replaces the current standard IAS 17, "Leases", and its associated interpretative guidance. Early adoption is permitted, provided the Company has adopted IFRS 15. This standard sets out a new model for lease accounting. A lessee can choose to apply IFRS 16 using either a full retrospective approach or a modified retrospective approach.

The Company adopted IFRS 16 on January 1, 2019 and did not identify any lease obligations. As a result, adopting this standard did not have an impact on the interim condensed consolidated financial statements.

# LIQUIDITY AND CAPITAL RESOURCES

At March 31, 2019, MBI had cash totalling \$931 and a working capital deficiency of \$153,381, compared to cash of \$2,398 and a working capital deficiency of \$133,817 at December 31, 2018. During the year ended December 31, 2011, under the terms of the Commercialization Agreement, Helomics<sup>TM</sup> paid to MBI license fees and research reimbursement, being \$2,292,589. Such amount paid by Helomics<sup>TM</sup> to MBI, not including research reimbursement allocated to such amount totaling over \$1 million, subject to MBI's obligation to pay to UHN royalties of a percentage in the high teens pursuant to the sublicensing of technology licensed by MBI from UHN (paid \$222,816 during the year ended December 31, 2011).

Cash from operating activities was \$1,240 for the three months ended March 31, 2019 compared to cash used in operating activities was \$2,245 for the three months ended March 31, 2018.

On January 13, 2015, the Company entered into a debt settlement agreement with the Chief Executive Officer ("CEO") and agreed to issue 265,252 common shares of the Company at a deemed price of \$0.40 (CAD\$0.50) per share, to settle payables of CAD\$132,626 that were owed to the CEO at December 31,

2014. The common shares were issued February 21, 2015. The fair value of the common shares was CAD\$185,676 (US\$149,006) on February 21, 2015 when the shares were issued and as a result, a loss on settlement of debt of CAD\$53,050 (US\$42,742) was recorded during the period.

In March 2014, as a result of MBI's cash position, the former board announced that the management and the directors of MBI had voluntarily elected to defer their cash compensation (not including reimbursement of expenses in the ordinary course) to provide an extended runway for the Company pending the anticipated payment by Helomics<sup>TM</sup> of the first milestone payment under the commercialization agreement. The cash compensation owing but not paid to management and directors was being accrued and was due and payable upon demand.

On September 4, 2014 former management and directors demanded payment and were paid \$75,427 (CAD \$83,225). The debt amount owing to former management and directors as of March 31, 2019 was \$6,948.

# FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

# Capital disclosure

The Company considers share capital, warrants, and equity reserves as capital. The Company's objectives when managing its capital structure are to provide sufficient capital to advance the commercialization of its products, meet the Company's obligations as they come due, and provide for the potential acquisition of additional intellectual property rights related to products within the Company's strategic plans.

The Company's officers and senior management take full responsibility for managing the Company's capital and do so through quarterly meetings and regular review of financial information. The Company's Board of Directors is responsible for overseeing this process.

The Company monitors its capital structure and may make adjustments to it in light of changes in the Company's operating performance, changes in economic conditions and the risk characteristics of the underlying assets. When adjustments to the capital structure are considered appropriate, such changes may include the issuance of new shares, issuance of new debt, or re-purchasing of shares for cancellation.

The Company is not subject to externally imposed capital requirements and there has been no change with respect to the overall capital risk management strategy during the current period. The method used by the Company to manage its capital has been the issuance of new share capital. Management does not foresee any changes to this in the future, however this cannot be assured.

#### Credit risk

Credit risk is the risk of an unexpected loss if a customer or third party to a financial instrument fails to meet its contractual obligations and arises principally from the Company's cash and cash equivalents and government contribution receivable. At present, the Company holds its cash in Canadian rated financial institutions and will only consider investment of excess cash in highly rated government and corporate debt securities or guaranteed certificates from Canadian chartered banks. The Company has established guidelines, including diversification, credit ratings and maturities, to ensure safety and liquidity of its cash. These guidelines are periodically reviewed by the Company's audit committee and modified to reflect changes in market conditions.

## Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they come due. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, the Board of Directors considers securing additional funds through issuances of equity and debt or partnering transactions. The Board of Directors approves the Company's annual operating and capital budgets as well as any material transactions outside the ordinary course of business. Management regularly reviews these budgets and maintains short-term cash flow forecasts. At March 31, 2019, the Company's current liabilities including accounts payable and due to related parties were \$163,264 (December 31, 2018 - \$137,282).

# Market risk

Market risk is the risk that changes in foreign exchange rates, interest rates and equity prices will affect the Company's future cash flows or valuation of its financial instruments. The Company is exposed to the financial risk related to the fluctuation of foreign exchange rates. Foreign currency risk is limited to the portion of the Company's business transactions denominated in currencies other than the Canadian dollar, primarily expenses for consulting, research and development work incurred in US dollars. The Company believes that the results of operations and cash flows would be affected by a sudden change in foreign exchange rates, but would not impair or enhance its ability to pay its US dollar denominated obligations. The Company does not currently view its exposure to US dollars as a significant risk due to the limited volume of transactions it conducts in this currency.

The Company is subject to interest rate risk on its cash and cash equivalents and believes its results of operations, financial position and cash flows would not be significantly affected by a sudden change in market interest rates relative to the investment interest rates due to the short-term nature of the investments. Excess cash is invested in highly rated investment securities at fixed interest rates with varying terms to maturity but generally with maturities of nine months or less from the date of purchase.

As at March 31, 2019, the Company held no cash equivalents. The Company does not invest in equity instruments of other corporations.

Changes in the Company's share price could impact its ability to raise additional capital.

# Fair value hierarchy

Financial instruments recognized at fair value on a recurring basis in the consolidated statement of financial position must be classified into one of the three following fair value hierarchy levels:

Level 1 – measurement based on quoted prices (unadjusted) observed in active markets for identical assets and liabilities;

Level 2 – measurement based on inputs other than quoted prices included in Level 1, that are observable for the asset and liability;

Level 3 – measurement based on inputs that are not observable (supported by little or no market activity) for the asset or liability.

The Company's financial instrument carrying amounts and fair values by levels per the fair value hierarchy (there were no changes from the prior year) are as follows:

	Fair Value Level	Ma	arch 31, 2019	Dec	ember 31, 2018
Financial assets Cash	1	\$	931	\$	2,398

#### INTERNAL CONTROLS OVER FINANCIAL REPORTING

# Changes in Internal Control over Financial Reporting ("ICFR")

In connection with National Instrument 52-109, Certification of Disclosure in Issuer's Annual and Interim Filings ("NI 52-109") adopted in December 2008 by each of the securities commissions across Canada, the Chief Executive Officer and Chief Financial Officer of the Company will file a Venture Issuer Basic Certificate with respect to financial information contained in the unaudited interim consolidated financial statements and the audited annual consolidated financial statements and respective accompanying Management's Discussion and Analysis. The Venture Issue Basic Certification does not include representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting, as defined in NI 52-109.

#### **RISKS AND UNCERTAINTIES**

Prospects for companies in the life science industry generally may be regarded as uncertain given the nature of the industry and, accordingly, investments in such companies should be regarded as highly speculative. Readers should carefully consider the risk factors and other information included herein. The risks and uncertainties described herein are not the only ones applicable. Additional risks and uncertainties not presently known to MBI or currently deemed immaterial may also impair the financial results of MBI. If any of the risks referred to herein or incorporated by reference herein actually occur, MBI's business, financial condition or results of operations could be materially adversely affected.

MBI is a commercial-stage company with a 12-year operating history, a marketable test and losses predicted for the foreseeable future until commercialization and a revenue stream is realized.

MBI's predecessor was founded in October 2002 and was amalgamated with MBI in April 2006. As such, MBI has a limited operating history and has not earned any profits to date. Since MBI's inception through March 31, 2019, it has incurred cumulative losses from operations of \$14,495,941. To date, MBI has not achieved, and it may never achieve, revenues sufficient to offset expenses. MBI expects to devote substantially all of its resources to managing the commercialization of its Signature.

Because of the numerous risks and uncertainties associated with commercializing a genomics test, MBI is unable to predict the extent of any future losses or when it will become profitable, if ever. MBI may never become profitable and shareholders may never receive a return on an investment in MBI's common shares. An investor in MBI's common shares must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of tests in the medical diagnostic industry. MBI may never successfully commercialize its Signature and MBI's business may fail.

# There are no assurances that MBI will be able to maintain operations until commercialization of its Signature. If unsuccessful in this respect, MBI may be forced to cease operations.

In order for MBI to maintain operations, MBI will need to retain enough cash resources to allow it to maintain operations for a sufficient period of time until expected licensing revenue from the commercialization of its Signature will be greater than MBI's operational costs. MBI cannot, with certainty, estimate or know the timing and extent of receipt of licensing revenues it Signature or the exact cash resources required by MBI to maintain operations until sufficient revenues are received by MBI, if at all. Until MBI can generate licensing revenues sufficient to finance its cash requirements, if at all, it will need to raise additional external funds through the sale of equity or debt securities or the merger or sale of MBI. The sale of such additional equity and debt securities may result in substantial dilution to the Shareholders or may not be available, if at all, in amounts or on terms acceptable to MBI. If additional capital is require and not obtained, MBI will be forced to cease operations.

# If the commercialization and development of the Signature fall short of market expectations, MBI's common share price may decline.

Periodically, MBI may forecast the timing of various commercial, scientific, clinical and regulatory accomplishments, including, among other things, the commercialization of the Signature and the timing and amounts of revenues to MBI, the conducting of additional studies on the Signature. All of these forecasts are based on a variety of assumptions, most of which are beyond MBI control. Actual results are likely to vary relative to such forecasts and, in many cases, could vary dramatically. If MBI does not achieve these forecasts as publicly announced, MBI's common shares may decline.

# MBI's near-term financial success and the market price of the common shares will depend upon successful commercialization of one Signature, and MBI will need to generate sufficient revenues from this to achieve profitability.

For the foreseeable future, MBI expects to derive substantially all of its revenues, if any, from the commercialization of its Signature. There can be no assurances that the commercialization will happen within an acceptable time period, if at all. If MBI is unable to successfully commercialize the Signature, MBI's future licensing revenues and ability to achieve profitability will be impaired, and the market price of the common shares could decline significantly.

# The long-term commercial success of the Signature will depend largely upon the extent to which payors, such as Medicare and Medicaid, and other third-party payors reimburse the test.

The long-term commercial success of the Signature will depend largely upon the extent to which, such as Medicare and Medicaid in the United States, and other third-party payors reimburse the test. In the United States, payors generally require evidence of both analytical and clinical validity (i.e. reliability of test results associated with the target disease) as well as clinical utility (i.e. whether the test results affect actual clinical decision-making and, possibly, improve patient outcomes) before reimbursing for a molecular diagnostic test.

The evidentiary requirements of payors in the United States relating to the clinical utility of high-value molecular diagnostic tests, which includes MBI's Signature, has recently been clarified after a number of years. Also, specific payors have recently declined coverage of some molecular diagnostic tests citing a lack of evidence of clinical utility in the submissions.

MBI expects to partner with a company or organization with experience in securing payor coverage. MBI cannot forecast the how successful a potential partner would be in securing payor coverage for the Signature, if at all.

MBI may take longer than expected to achieve successful commercialization of the Signature and at within such time that MBI expects, if at all.

Successful commercialization of the Signature will depend upon securing a partnership with a company or organization who can leverage their commercial and clinical experience and infrastructure relating to test development, laboratory operations, sales, marketing, reimbursement and regulatory compliance. This may take longer than expected to and such partnership may not result in the benefits that MBI expects, if at all.

Should a potential partner commercialize the Signature, they may not gain acceptance among physicians, healthcare professionals and third-party payors, which could have a material impact on MBI's licensing revenues and business.

Should a potential partner commercialize the Signature as a clinical service in the United States and internationally, its success will depend upon the test being accepted in the market. The degree of market acceptance of the test by physicians, healthcare professionals and third-party payors will depend on a number of factors, including:

- acceptance of acceptance of the Signature using whatever medium is chosen by the commercialization partner;
- The ability to provide acceptable evidence of clinical utility;
- successful integration into clinical practice;
- availability and advantages of alternative tests;
- effectiveness of the partner's sales and marketing efforts and strategies;
- pricing and positive health economics; and
- The partner's ability to obtain sufficient insurance coverage or reimbursement.

If the Signature fails to gain market acceptance, MBI's ability to generate licensing revenue would be impaired, which could have a material impact on its business, financial condition and operations.

If the partner not able to offer the Signature at a price that they or MBI deem appropriate, or if there is a general decrease in the prices of molecular diagnostics tests, then the partner may need to lower its price, which could have a material adverse impact on MBI's licensing revenue and business.

If the partner is able to commercialize the Signature, we expect to receive revenue based upon a percentage of the partner's net sales of the Signature. The sales price at which the partner offers the Signature will, to a certain extent, depend upon the expected clinical utility and positive health economics of the test, along with the prices charged for other marketed molecular diagnostic tests. If the partner is not able to offer the Signature at a price that it deems appropriate, or if there is a general decrease in the prices of molecular diagnostics tests, then the partner may need to lower its price, which could have a material adverse impact on MBI's licensing revenue and business, financial condition and operations.

If MBI is unable to adequately prosecute its patent rights relating to the Signature, its competitive position could be impaired and MBI's licensing revenues and business could be negatively impacted.

There is no guarantee that other companies will not independently develop tests similar to GeneFx® Lung, that they will not imitate the test or that competitors will not produce tests designed to circumvent MBI's proprietary rights. Certain of the genes utilized in the Signature may be covered by patents or patent applications of other parties. However, other potential products could produce the same results as the Signature without infringing on MBI's patents. Such a situation could have a material adverse impact on MBI's licensing revenue and business.

The industry in which the Signature operates is highly regulated and the failure or delay in obtaining and maintaining regulatory approvals could adversely affect its ability to commercialize the Signature.

The industry in which the Signature operates is highly regulated. Ultimate commercial success may be dependent upon the ability to obtain the necessary regulatory approvals for the Signature. The task of obtaining appropriate regulatory clearance or approval for tests may be time consuming. There is no guarantee that the test will meet the applicable regulatory standard. The regulatory clearance or approval process may also require the expenditure of substantial resources is uncertain and subject to delays. In addition, approval by a regulatory authority in one country does not ensure the approval by regulatory authorities of other countries. Failure or delays in obtaining regulatory clearances or approvals could adversely affect MBI's ability to commercialize the Signature and MBI's ability to generate licensing revenue.

If the U.S. Food and Drug Administration were to begin regulating genomic tests, MBI and/or its potential partner could incur substantial costs and time delays associated with meeting requirements for pre-market clearance or approval and/or experience decreased demand for or reimbursement of the Signature.

Clinical laboratory tests are regulated in the United States under CLIA as well as by applicable state laws. Diagnostic kits that are sold and distributed through interstate commerce are regulated as medical devices by the U.S. Food and Drug Administration ("FDA"). Clinical laboratory tests that are developed and validated by a laboratory for its own use are called laboratory developed tests, or LDTs. Most LDTs currently are not subject to FDA regulation, although reagents or software provided by third parties and used to perform LDTs may be subject to regulation.

MBI cannot provide any assurance that FDA regulation, including pre-market review, will not be required in the future for the Signature, either through new policies adopted by the FDA or new legislation enacted by the United States Congress. It is possible that legislation will be enacted into law and may result in increased regulatory burdens for MBI to offer or continue to offer the Signature as a clinical laboratory service.

If the FDA decides to regulate the Signature, it may require that MBI or its partner conduct extensive premarket clinical studies prior to submitting a regulatory application for commercial sales. If MBI or its partner is required to conduct pre-market clinical studies, whether using retrospectively collected and banked samples or prospectively collected samples, delays in the commencement or completion of clinical studies could significantly delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical studies may also ultimately lead to delay or denial of regulatory clearance or approval.

The commencement of clinical studies may be delayed due to insufficient patient enrolment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial. MBI or its partner may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of its clinical studies, which might increase the cost of the studies. MBI or its partner may also depend on clinical investigators, medical institutions and contract research organizations to

perform the studies properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to MBI or its partner's clinical protocols, FDA requirements or for other reasons, MBI or its partner's clinical studies may have to be extended, delayed or terminated. Many of these factors would be beyond MBI or its partner's control. MBI or its partner may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing as a result of the failure to perform by third parties, MBI or its partner's research and development costs would increase, and they may not be able to obtain regulatory clearance or approval for the test. In addition, MBI or its partner may not be able to establish or maintain relationships with these parties on favourable terms, if at all. Each of these outcomes would harm MBI or its partner's ability to market the test and MBI's ability to generate licensing revenues from sales of the test.

# Fluctuations in exchange rates could result in foreign currency exchange losses.

Substantially all of MBI's expenses are currently denominated in Canadian dollars, while a portion of its expenses are denominated in foreign currencies, primarily in U.S dollars. Fluctuations in exchange rates, particularly those involving the U.S. dollar, may affect MBI's costs. Where MBI's operations conducted in Canadian dollars are reported in U.S. dollars, such fluctuations could result in changes in reported results which do not reflect changes in the underlying operations. As substantially all of its current expenses are denominated in Canadian dollars, any potential future appreciation of the Canadian dollar against the U.S. dollar could adversely affect MBI's results of operations. The fluctuation of foreign exchange rate affects the value of these monetary assets and liabilities denominated in U.S. dollars. Generally, an appreciation of the Canadian dollar against the U.S. dollar results in a foreign exchange loss for monetary assets denominated in U.S. dollars, and a foreign exchange gain for monetary liabilities denominated in U.S. dollars. On the contrary, a devaluation of the Canadian dollar against the U.S. dollar results in a foreign exchange gain for monetary assets denominated in U.S. dollars and a foreign exchange loss for monetary liabilities denominated in U.S. dollars. MBI has not entered into any hedging transactions to reduce its exposure to foreign currency exchange risk. While MBI may decide to enter into hedging transactions in the future, the availability and effectiveness of these hedges may be limited and it may not be able to successfully hedge all or part of its exposure or at all.

# MBI's common shares have historically been thinly traded and shareholders may be unable to sell at or near ask prices or at all if they desire to liquidate their shares.

MBI's common shares are currently listed on the TSX Venture Exchange and have historically been "thinly-traded", meaning that the number of persons interested in purchasing its common shares at or near bid prices at any given time may be relatively small. This situation is attributable to a number of factors, including the fact that MBI is currently a pre-revenue-stage company which is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if MBI came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow a pre-revenue-stage company such as MBI or purchase or recommend the purchase of MBI's common shares until such time as it generates revenue. As a consequence, there may be periods of several days or more when trading activity in MBI's common shares is minimal, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. MBI cannot give assurances that a broader or more active public trading market for our common shares will develop or be sustained. As a result, shareholders may be unable to sell their common shares at or above their purchase price if at all, which may result in substantial losses to them.

## SHAREHOLDER'S EQUITY AND OUTSTANDING SHARE DATA

The authorized share capital of MBI consists of an unlimited number of common shares. MBI had outstanding common shares, stock options, and warrants (exercise prices, which are in Canadian dollars, have been converted to U.S. dollars at the March 31, 2019 rate of U.S. \$1.00 = C\$1.33).

On December 19, 2017, the Company effected a previously approved one-for-ten consolidation of all its issued and outstanding common shares. All share and per-share data presented in the Company's consolidated financial statements and notes have been retrospectively restated to reflect the share consolidation unless otherwise noted. The exercise price and number of common shares issuable pursuant to all outstanding stock options and warrants have been adjusted in accordance with the consolidation ratio.

As at the date of this report, the Company had the following outstanding:

- 8,757,835 common shares
- Stock options:

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Number of options	Exercisable	Exercise price	Expiry date
375,000	375,000	CAD \$0.50	November 19, 2025
775,000	775,000	CAD \$0.50	January 3, 2027
100,000	100,000	CAD \$0.50	February 17, 2027
1,250,000	1,250,000		

#### • Warrants:

Number of warrants	Exercisable	Exercise price \$	Expiry date
100,000	100,000	CAD \$0.65	May 12, 2021

#### **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no off-balance sheet arrangements.

#### PROPOSED TRANSACTIONS

There are no proposed transactions that have not been disclosed herein.

# CRITICAL ACCOUNTING ESTIMATES

The preparation of condensed consolidated interim financial statements in accordance with IFRS requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the condensed consolidated interim financial statements and the reported amounts of revenue and expenses during the reporting period. Actual reports could differ from management's estimates.

#### **CONTINGENCIES**

There are no contingent liabilities.

#### MANAGEMENT'S RESPONSIBILITY FOR FINANCIAL STATEMENTS

The information provided in this report, including the consolidated financial statements, is the responsibility of management. In the preparation of these statements, estimates are sometimes necessary to make a determination of future values for certain assets or liabilities. Management believes such estimates have been based on careful judgments and have been properly reflected in the consolidated financial statements.

# OTHER MD&A REQUIREMENTS

Additional disclosure of the Company's technical reports, material change reports, news releases and other information can be obtained on SEDAR at www.sedar.com.

# **DIRECTORS AND OFFICERS**

Dr. Iain Weir-Jones, *Chief Executive Officer, Chairman of the Board* Ibrahim Ghobrial, *Chief Financial Officer, Corporate Secretary* Dr. Terence W. Friedlander, M.D., *Director* Toby Weir-Jones, *Director* David Diebolt, *Director* Shumsheer Sidhu, *Director*