

## **MANAGEMENT'S DISCUSSION & ANALYSIS**

# FOR THE THREE AND SIX MONTHS ENDED JUNE 30, 2015 and 2014

Dated: August 31, 2015

One Carlson Parkway, Suite 124 Minneapolis, Minnesota, 55447 www.diamedica.com

#### **Management's Discussion and Analysis**



All references in this management's discussion and analysis ("MD&A") to "the Company", "DiaMedica", "we", "us", or "our" refer to DiaMedica Inc. and the subsidiaries through which it conducts its business, unless otherwise indicated.

The following MD&A is prepared as of August 31, 2015 for DiaMedica for the six months ended June 30, 2015 and 2014 and should be read in conjunction with the unaudited condensed consolidated interim financial statements for the six months ended June 30, 2015 and 2014 and the audited consolidated financial statements and accompanying notes for the years ended December 31, 2014 and 2013, which have been prepared by management in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). This MD&A also should be read in conjunction with the Company's Annual Information Form dated April 30, 2015. Additional information regarding the Company is available on SEDAR at http://www.sedar.com and on the Company's website at http://www.diamedica.com.

All amounts are in Canadian dollars, unless otherwise indicated.

#### GOING CONCERN

The Company's consolidated financial statements have been prepared using IFRS that are applicable to a going concern, which contemplates the realization of assets and settlement of liabilities and commitments in the normal course of business as they come due. There is substantial doubt about the appropriateness of the use of the going concern assumption because the Company has experienced operating losses and cash outflows from operations since incorporation, has an accumulated deficit of \$46.1 million, a net asset deficiency of \$1.2 million and a working capital deficiency of \$84,911 as of June 30, 2015. Further, its cash resources are not sufficient for the next twelve months of planned operations, additional funding will be required in order to continue its research and development and other operating activities and it has not reached successful commercialization of its products. The Company's ability to continue as a going concern is dependent on its ability to continue obtaining sufficient funds to conduct its research and development, and to successfully commercialize its products.

The Company is expanding its direction with its lead product based on the results of its Phase 2 trials for its use in the treatment of diabetes. While the trial achieved the primary endpoint of demonstrating the safety of the compound, it did not achieve the secondary objective of improvement in glucose control. Therefore, the company has suspended further work in pursuing the use of DM199 for a diabetes treatment and is now focused on the development of DM199 for the treatment of acute ischemic stroke and other vascular diseases.

The Company's future operations are therefore dependent upon its ability to generate product revenues, negotiate license agreements with partners, and secure additional funds. There can be no assurance that the Company will be successful in commercializing its products, entering into strategic agreements with partners, or raising additional capital on favorable terms or at all. While the Company completed two private placements in the first half of 2015 (see Corporate Developments) and has taken measures to preserve, the Company will not have enough cash on hand to sustain operations beyond the end of December 2015 unless further funds have been raised. Further, there can be no assurance that the Company will be successful in raising additional capital on favorable terms or at all. The availability of financing will be affected by the results of scientific and clinical research, the ability to attain regulatory approvals, the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies and other relevant commercial considerations. If the Company cannot secure additional financing on favorable terms or at all, the Company will have to consider additional strategic alternatives beyond the cost saving measures described above. Such additional strategies may include delays of product development expenditures, exploring the monetization of certain intangible assets, as well as seeking to out-license and/or divest assets through a merger, sale or liquidation of the Company.

The ability of the Company to continue as a going concern and to realize the carrying value of its assets and settle its liabilities and commitments when due is dependent on many factors, including, but not limited to the successful completion of the actions taken or planned, some of which are described above, which are intended to mitigate the adverse conditions and events which raise substantial doubt about the validity of the going concern assumption used in preparing these consolidated financial statements. There can be no assurance that the Company will be able to

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obtain sufficient financing to meet future operational needs or that the above described and other strategies will be sufficient to permit the Company to continue as a going concern.

The Company's condensed consolidated interim financial statements for the three and six months ended June 30, 2015 do not reflect adjustments in the carrying values of the Company's assets and liabilities, expenses, and the balance sheet classification used, that would be necessary if the going concern assumption was not appropriate. Such adjustments could be material.

## CAUTIONARY STATEMENT ABOUT FORWARD-LOOKING STATEMENTS

This MD&A contains forward-looking statements within the meaning of applicable securities laws. All statements, other than statements of historical facts, included in this MD&A regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words "believe", "anticipate", "estimate", "plan", "expect", "intend", "may", "project", "will", "would" and similar expressions and the negative of such expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We cannot guarantee that we actually will achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements.

The Company's statements of "belief" in respect of our drug candidates are based primarily upon our results derived to date from our preclinical and clinical research and development program. We also use the term "demonstrated" in this MD&A to describe certain findings that we make arising from our research and development including any preclinical and clinical studies that we have conducted to date.

The Company believes that it has a reasonable scientific basis upon which we have made such statements of "belief" or arrived at such findings. It is not possible, however, to predict, based upon *in vitro* and/or animal studies whether a new therapeutic agent or a second generation compound(s) will be proved to be safe and/or effective in humans and no conclusions should be drawn in that regard from what we state has been demonstrated by us to date. We cannot assure you that the particular results expected by us will occur.

There are a number of important factors that could cause our actual results to differ materially from those indicated or implied by forward-looking statements or statements of "belief", including the factors discussed under "Risk Factors" and in other sections of this MD&A. These factors and the other cautionary statements made in this MD&A should be read as being applicable to all related forward-looking statements and statements of "belief" wherever they appear in this MD&A.

Any forward-looking statements and statements of "belief" represent our estimates only as of the date of this MD&A and should not be relied upon as representing our estimates as of any subsequent date. Except as required by law, the Company does not assume any obligation to update any forward-looking statements or statements of "belief". We disclaim any intention or obligation to update or revise any forward-looking statements or statements of "belief", whether as a result of new information, future events or otherwise except as otherwise required by law.

Such forward-looking statements involve known and unknown risks and uncertainties, including those referred to in this MD&A or in any document incorporated by reference herein, which may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Events or circumstances could cause our actual results to differ materially from those estimated or projected and expressed in, or implied by, these forward-looking statements. You also should consider carefully the matters discussed under "Risk Factors" in this MD&A. Additional risk factors are described in our current AIF. We undertake no obligation to update publicly or otherwise revise any forward-looking statements or the foregoing list of factors, whether as a result of new information or future events or otherwise, except as required by securities legislation.



#### **BUSINESS**

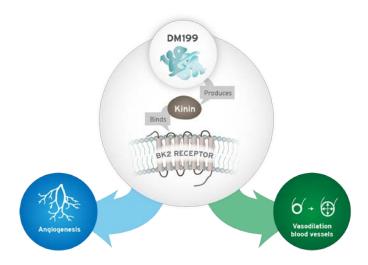
#### **Overview**

DiaMedica is a clinical stage biopharmaceutical company focused on large unmet diseases including novel approaches to treat acute vascular disease of the brain, kidney and heart. The primary near term focus is on acute ischemic stroke ("AIS") then potentially expanding into other vascular diseases such as acute kidney injury ("AKI"). DiaMedica's lead product, DM199, is a recombinant human tissue kallikrein-1 protein ("rhKLK1") treatment engineered to improve endothelial function by vasodilation and by inducing new blood vessel growth (angiogenesis).

A variety of catastrophic medical events such as a heart attack, acute kidney injury or stroke are a result of sudden reduced blood flow (ischemia), and endothelial dysfunction, which can lead to damaging inflammation and hypoxia at the cellular level. These events can begin from a variety of factors such as blood clot formation, sudden low blood pressure or trauma.

Published preclinical and clinical research with a naturally occurring tissue kallikrein-1 (KLK-1), extracted from human urine, has demonstrated the activities of increased vasodilation and collateral circulation (improved blood flow), increased angiogenesis, reduced cell death and reduced inflammation. Based on these findings, DM199, a recombinant form of tissue kallikrein-1, has the potential to treat a broad spectrum of clinical scenarios where reestablishing blood flow, reducing inflammation, and increasing angiogenesis in patients is vital to preserving organ function (e.g. brain, kidney and heart). Lower tissue kallikrein-1 levels in the blood have also been independently associated with first-ever stroke and are an independent predictor of recurrence after an initial stroke.

#### DM199 Mechanism of Action



Stroke represents an area of tremendous unmet medical need. Published preclinical and clinical research with a naturally occurring tissue kallikrein-1 has demonstrated the activities of increased vasodilation and collateral circulation (improved blood flow), increased angiogenesis, reduced cell death and reduced inflammation. As such, DiaMedica's recombinant form of tissue kallikrein-1 has the potential to treat a broad spectrum of clinical scenarios where re-establishing blood flow and reducing inflammation in patients is vital to preserving organ function (e.g.

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brain, kidney and heart). Lower tissue kallikrein-1 levels in the blood have also been independently associated with first-ever stroke and are an independent predictor of recurrence after an initial stroke.

#### **Outlook**

The Company is pursuing the development of DM199 in acute vascular disease of the brain, kidney and heart with AIS as the lead initiative. The Company is preparing to initiate clinical trials comparing DM199 to Kallikang (human urine extracted tissue kallikrein-1 approved for for the treatment of acute ischemic stroke in China). This to be followed by a Phase II clinical trial in patients wo have been inflicted with acute ischemic stroke. The Company may decide to accelerate, terminate or reduce its focus in certain research areas, or commence research in new areas as a result of the Company's research progress and the availability of financial resources. These decisions are made with the goals of managing the Company's cash resources and optimizing the Company's opportunities. Long-term, the Company will continue to seek to maximize shareholder value by advancing early-stage therapeutic agents to clinical testing and validation, with the goal of establishing late-stage development and commercialization partnerships with major pharmaceutical companies.

DiaMedica believes their proprietary manufacturing process of DM199 (recombinant human KLK-1), allows for a higher purity and lower cost of goods product in comparison to HUK while also addressing any potential supply constraints. These factors make DM199 a better-positioned product for regulatory approval worldwide as a recombinant protein is able to meet the rigorous manufacturing standards required for approval in comparison to a urine-derived protein .

#### **Trend Information**

Historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures and therefore liquidity and capital resources vary substantially from period to period depending on the timing of manufacturing, and the initiation and completion of preclinical and clinical studies being undertaken at any one time and the availability of funding from investors and prospective commercial partners.

Other than as discussed above, the Company is not aware of any material trends related to the Company's business of product development, patents and licensing.

#### **Corporate Developments**

On July 16, 2015, the Company announced that the Company's stock will trade on the OTCQB Exchange under the symbol "DMCAF" as part of its long-term strategy to introduce the company to a broader range of institutional and retail investors in the U.S.

On June 19, 2015, the Company completed a non-brokered private placement of 9,750,000 units at a price of \$0.10 per unit for aggregate gross proceeds of approximately \$975,000. Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant will entitle the holder thereof to purchase one additional common share for the price of \$0.20 prior to June 19, 2016. In connection with the financing, the Company issued 420,000 compensation warrants and paid a finder's fee of 5% of the aggregate gross proceeds. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.10 prior to expiry on June 19, 2016.

On March 13, 2015, the Company completed a non-brokered private placement of 6,000,000 units at a price of \$0.10 per unit for aggregate gross proceeds of approximately \$600,000. Each unit consisted of one common share. In connection with the financing, the Company issued 227,350 compensation warrants and paid finder's fee of 5% of the aggregate gross proceeds. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.10 prior to expiry on March 13, 2016.

#### **Management's Discussion and Analysis**



On February 2, 2015, the Company announced it would pursue the development of DM199 towards acute vascular disease of the brain, kidney and heart. The primary focus will be on AIS and acute kidney injury indications. DM199 has the potential to treat a broad spectrum of clinical scenarios where re-establishing blood flow and reducing inflammation in patients is vital to preserving organ function (e.g. brain, kidney and heart).

#### DM199 in Acute Ischemic Stroke (AIS)

AIS is the result of an acute blot clot formation leading to blood vessel blockage in the brain. The resulting ischemia leads to brain damage and death. A stroke can lead to permanent damage with memory loss, speech problems, reading and comprehension difficulties, physical disabilities and emotional behavioral problems being commonly observed outcomes.

At the site of blood flow blockage, there exist two major ischemic zones - the core ischemic zone with only 10-25% blood flow, and the surrounding ischemic penumbra having partially reduced blood flow (Stroke. 2011 Jan;42(1 Suppl):S7-11). The core zone neuronal cells die from apoptosis (excitotoxicity) within minutes of stroke onset. The ischemic penumbra zone however may remain viable for several hours via collateral arteries that branch from the main occluded artery in the core zone. Unfortunately, penumbra zone neuronal cell death eventually occurs as collateral blood supply is inadequate to maintain cellular function indefinitely. As such, next generation stroke therapies are being developed to protect the viable cells of the penumbra with anti-apoptotic, pro-angiogenesis, or immunodulation functions during the hours to a week after a stroke (Int J Stroke. 2012 Jul;7(5):426-34. And Stroke. 2011 Jan; 42(1 Suppl):S7-11).

According to the World Health Organization (WHO), each year about 15 million people worldwide fall victim to a stroke - of which 5.5 million will die and 5.0 million will be permanently disabled (WHO Cardiovascular Disease Atlas 16). According to the US Centers for Disease Control, in the US alone stroke kills almost 130,000 patients per year and is a leading cause of serious long-term disability (www.cdc.gov/stroke/faqs.html accessed April 2015). In addition the cost including health care services, medications and lost productivity is estimated to be around \$34 billion (Circulation. 2015; e29-322).

The only approved therapy in the US, tissue plasminogen activator (tPA) clot buster, is used on only 5-7% of those with an ischemic stroke with a limited 3-4.5-hours post-stroke therapeutic window of the therapy (Stroke. 2009 Aug;40(8):2945-8). As such, additional therapeutic options are of great needed. DM199 is being positioned to treat acute ischemic stroke patients up to 48 hours after an ischemic stroke where there are no treatment options available today. DM199 may also be effective when administered in combination with tPA.

The company is in initial discussions for potential collaborations for the use of DM199 in the treatment of acute ischemic stroke for certain regions of the world.

#### DM199 in Acute Kidney Injury (AKI)

AKI is the sudden loss of kidney function over a 1-2 day period of time. This loss of function is measured by an increase in serum creatinine and decrease in urine output. Reduced blood flow into the kidney or damage within the kidney (inflammation or necrosis) limits the ability to filter blood.

AKI occurs in approximately 20-67% of patients admitted to the intensive care unit (Drug Discovery World Spring 2014: 26-31) leading to ~\$10 billion in annual US-based hospital costs (J. Am. Soc. Nephrol. 2005;16:3365-3370). Additionally, patients with AKI are more likely to progress to chronic kidney disease and end-stage renal disease. As such, there is an estimated ~2 million cases of hospital setting AKI each year in the western world, with a mortality rate ranging from 15-60%. The most common causes of AKI are sepsis, burns, trauma, heart attack or heart surgery, imaging contrast agents, nephrotoxic drugs (e.g. chemotherapeutics, antibiotics, NSAIDs).





Currently, there are no therapeutic options to treat or prevent the onset of AKI. In a preclinical model of AKI, it was shown that intravenous injection of KLK-1 helped to reduce renal cell apoptosis, inflammation, renal dysfunction (Toxicol. Sci. (2008) 102(2): 433-443) compared to control. DM199 has the potential to be effective in preserving kidney function or limiting the damage caused from AKI.RESULTS OF OPERATIONS

#### For the three and six months ended June 30, 2015 and 2014.

Since inception, the Company has incurred losses while advancing the research and development of its therapeutic products. Net loss for the six months ended June 30, 2015 was \$978,624 compared to a loss of \$3,555,021 for the six months ended June 30, 2014. The decrease in net loss for the six months ended June 30, 2015 over the comparable period of the prior year was due mainly to lower DM199 development costs.

#### **Research and Development**

Components of research and development expenses for the three months ended June 30, 2015 were as follows:

	2015	2014
	\$	\$
Research and development programs, excluding the below	87,912	650,207
Salaries, fees and short-term benefits	128,918	292,310
Share-based compensation	34,825	63,336
Depreciation of property and equipment	469	1,885
Government assistance	nil	nil
	252,124	1,007,738

Components of research and development expenses for the six months ended June 30, 2015 were as follows:

	2015	2014
	\$	\$
Research and development programs, excluding the below	199,605	2,042,102
Salaries, fees and short-term benefits	375,675	707,614
Share-based compensation	59,843	143,323
Depreciation of property and equipment	3,640	2,392
Government assistance	nil	(36,253)
	638,763	2,859,178

As part of the ongoing review of the Company's portfolio of intellectual property, an impairment loss totaling \$323,077 was recognized on certain patents for the year ended December 31, 2014. During 2014, the Company successfully completed Phase IIa clinical trial of DM199. While the trial achieved the primary endpoint of demonstrating the safety of the compound, it did not achieve the secondary objective of improvement in glucose control. Therefore, the Company's near term focus in the treatment of AIS and other vascular diseases. The current year write-down related to patent costs for filings on indications the Company no longer intends to pursue as a result of shifting its focus and development plans.

#### **Management's Discussion and Analysis**



#### **General and Administrative**

Components of general and administrative expenses for the three months ended June 30, 2015 were as follows:

	2015	2014
	<b>\$</b>	\$
General and administrative, excluding the below	112,636	254,925
Salaries, fees and short-term benefits	19,484	22,338
Share-based compensation	18,301	47,708
	150,421	324,971

Components of general and administrative expenses for the six months ended June 30, 2015 were as follows:

	2015	2014
	\$	\$
General and administrative, excluding the below	195,740	573,148
Salaries, fees and short-termbenefits	33,927	41,073
Share-based compensation	47,979	84,191
	277,646	698,412

General and administration expenses for the six months ended June 30, 2015 decreased over the comparable period due mainly to plans implemented during fourth quarter and subsequent which resulted in a reduction in pay for employees and the elimination of certain positions.

#### Finance income and finance costs

Finance income for the six months ended June 30, 2015 of \$49,008 was higher than the same period of 2014 amount of -\$56,894 due to foreign exchange gains.

#### LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has financed its operations from public and private sales of equity, the exercise of warrants and stock options, interest income on funds available for investment and government grants and tax credits. As at June 30, 2015, the Company had cash and cash equivalents totaling \$568,759 compared to \$339,627 at March 31, 2015.

#### Common shares issued – for the six months ended June 30, 2015

On March 13, 2015, the Company completed a non-brokered private placement of 6,000,000 units at a price of \$0.10 per unit for aggregate gross proceeds of approximately \$600,000. Each unit consisted of one common share. In connection with the financing, the Company issued 227,350 compensation warrants and paid a finder's fee of 5% of the aggregate gross proceeds. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.10 prior to expiry on March 13, 2015.

On June 19, 2015, the Company completed a non-brokered private placement of 9,750,000 units at a price of \$0.10 per unit for aggregate gross proceeds of approximately \$975,000. Each unit consisted of one common share and one-half common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$0.20 at any time prior to expiry on June 19, 2016. In connection with the financing, the Company issued 420,000 compensation warrants and paid a finder's fee of 5% of the aggregate gross proceeds. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.10 prior to expiry on June 19, 2016.

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The \$0.10 unit issue price was allocated to common shares in the amount of \$0.08 per common share and the unit warrants were allocated a price of \$0.02 per half-warrant. The costs of the issue were allocated on a pro rata basis to the common shares and unit warrants. Accordingly, \$685,535 was allocated to common shares and \$215,454 to the unit warrants, net of issue costs. Assumptions used to determine the value of the unit warrants were: dividend yield 0%; risk-free interest rate 0.59%; expected volatility 202%; and average expected life of 12 months. Assumptions used to determine the value of the compensation warrants were: dividend yield 0%; risk-free interest rate 0.59%; expected volatility 202%; and average expected life of 12 months.

#### Common shares issued – for the year ended December 31, 2014

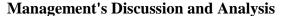
On January 3, 2014, the Company completed a non-brokered private placement of 154,500 units at a price of \$0.90 per unit for aggregate gross proceeds of \$139,050 (\$116,046 net of issue costs). Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant will entitle the holder thereof to purchase one additional common share for the price of \$1.10 at any time prior to expiry on December 23, 2015, subject to acceleration of the expiry date of such warrants in certain circumstances. In connection with the financing, the Company issued 9,270 compensation warrants and paid a finder's fee of 6% of the aggregate gross proceeds. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$1.10 prior to expiry on January 3, 2015.

The \$0.90 unit issue price was allocated to common shares in the amount of \$0.80 per common share and the unit warrants were allocated a price of \$0.10 per half-warrant. The costs of the issue were allocated on a pro rata basis to the common shares and unit warrants. Accordingly, \$103,152 was allocated to common shares and \$12,894 to the unit warrants, net of issue costs. Assumptions used to determine the value of the unit warrants were: dividend yield 0%; risk-free interest rate 1.1%; expected volatility 59%; and average expected life of 24 months. Assumptions used to determine the value of the compensation warrants were: dividend yield 0%; risk-free interest rate 1.1%; expected volatility 57%; and average expected life of 12 months.

On January 22, 2014, the agent in connection with the offering completed on December 23, 2013, partially exercised its over-allotment option resulting in the issuance of an additional 31,000 units at a price of \$0.90 per unit for aggregate gross proceeds of \$27,900 (\$24,598 net of issue costs). Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$1.10 at any time prior to expiry on December 23, 2015, subject to acceleration of the expiry date of such warrants in certain circumstances. In connection with exercising of the over-allotment option, the Company issued 1,860 compensation warrants. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.90 prior to expiry on January 30, 2015.

The \$0.90 unit issue price was allocated to common shares in the amount of \$0.81 per common share and the unit warrants were allocated a price of \$0.09 per half-warrant. The costs of the issue were allocated on a pro rata basis to the common shares and unit warrants. Accordingly, \$22,138 was allocated to common shares and \$2,460 to the unit warrants, net of issue costs. Assumptions used to determine the value of the unit warrants were: dividend yield 0%; risk-free interest rate 1.0%; expected volatility 54%; and average expected life of 24 months. Assumptions used to determine the value of the compensation warrants were: dividend yield 0%; risk-free interest rate 1.0%; expected volatility 60%; and average expected life of 12 months.

On May 27, 2014, the Company completed a prospectus offering of 3,099,200 units at a price of \$0.70 per unit, for aggregate gross proceeds to the Company of \$2,169,440 (\$1,693,310 net of issuance costs). Each unit consisted of one common share and one half of one common share purchase warrant. Each whole warrant entitles the holder to purchase one common share at a price of \$1.00 at any time prior to expiry on May 27, 2016. The warrant expiry date can be accelerated at the option of the Company, in the event that the volume-weighted average trading price of the Company's common shares exceeds \$1.75 per common share for any 10 consecutive trading days. In connection with the financing, the Company issued 216,944 compensation warrants. Each compensation warrant entitles the holder to acquire one common share at an exercise price of \$0.70 prior to expiry on November 27, 2015.





The \$0.70 unit issue price was allocated to common shares in the amount of \$0.65 per common share and the unit warrants were allocated a price of \$0.05 per half-warrant. The costs of the issue were allocated on a pro rata basis to the common shares and unit warrants. Accordingly, \$1,572,359 was allocated to common shares and \$120,951 to the unit warrants, net of issue costs. Assumptions used to determine the value of the unit warrants were: dividend yield 0%; risk-free interest rate 1.1%; expected volatility 53%; and average expected life of 24 months. Assumptions used to determine the value of the compensation warrants were: dividend yield 0%; risk-free interest rate 1.1%; expected volatility 56%, respectively; and average expected life of 18 months.

During the year ended December 31, 2014, 86,135 common shares were issued on the exercise of warrants for gross proceeds of \$77,522.

#### Use of Proceeds Variance Analysis - December 2013 Offering and May 2014 Offering

The following table shows the estimated allocation of net proceeds from the offering of units completed by the Company on December 16, 2013 for gross proceeds of \$2,600,019 (the "December Offering") and the net proceeds from the May Offering and the actual use of net proceeds for the period commencing January 1, 2014 through December 31, 2014. The Company announced a capital raise on October 22, 2014 that was cancelled on November 5, 2014.

	Estimated Allocation of Net Proceeds from the December Offering	Estimated Allocation of Net Proceeds from the May Offering	Actual Allocation of Net Proceeds from January 1, 2014 through December 31, 2014	Variance
DM199				
Phase II trial & additional preclinical indications	\$1,272,155	\$1,315,000	\$2,307,686	\$279,469
DM204				
Preclinical development	50,000	\$Nil	\$99,894	(49,894)
General Working Capital Purposes and General & Administrative				
Expenses	\$808,033	\$378,310	\$1,415,918 <sup>(1)</sup>	(\$229,575)
Total	\$2,130,188	\$1,693,310	\$3,823,498	nil

#### Note:

#### Variance Analysis

In 2014, the actual allocation of net proceeds on DM199 for the Phase II trial and additional preclinical indications was less than the original estimated allocation of the December Offering and May Offering by approximately \$279,469 primarily due to timing of payments. The payments to the CRO conducting the trial are based on the achievement of various contract milestones. In addition, the Company deferred the pursuit of additional preclinical studies for DM199 in support of additional indications.

General working capital uses include primarily personnel and personnel-related costs. Research and development salaries are included in research and development expenses in the consolidated financial statements. In 2014, the actual allocation of net proceeds on general working capital purposes and general and administrative expenses was higher than the original estimated allocation of the December Offering and May Offering by approximately \$229,575 driven primarily by professional expenses associated with capital markets transactions, including the application to register the Common Shares with the SEC and investor relations costs.

<sup>(1)</sup> General working capital amount of \$1,415,918 includes research and development salaries and benefits of \$1,036,617.

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#### **Common Shares**

The continuity of the number of issued and outstanding common shares of the Company for the six months ended June 30, 2015, and to the date of this MD&A is presented below:

Balance, December 31, 2014	62,025,430
Shares issued under private placement	6,000,000
Balance, March 31, 2015	68,025,430
Shares issued under private placement	9,750,000
Balance, June 30, 2015	77,775,430

#### **Stock Options**

The Company has a stock option plan which is administered by the Board of Directors of the Company with stock options granted to directors, management, employees and consultants as a form of compensation. 7,000,000 common shares were reserved for issuance under the plan. Options granted vest at various rates and have terms of up to 10 years.

The following table reflects the activity under the Company's stock option plan for the six months ended June 30, 2015:

	Number of Options	2015 Weighted average exercise price
Balance, beginning of period	4,573,000	\$ 0.99
Granted	-	-
Exercised	-	-
Forfeited	-	-
Expired/cancelled	(1,042,500)	0.84
Balance, June 30, 2015	3,530,500	1.04
Options exercisable, end of period	3,088,666	1.07

#### Warrants

The following tables reflect the activity of the warrants for the six months ended June 30, 2015, and the closing balance reflects the potential cash proceeds from the outstanding warrants if they were to be exercised:

Type of Warrant	Comp	Unit	Unit	Unit Comp Unit Unit U		Unit	Comp	
Exercise Price	\$0.70	\$1.10	\$1.10 \$0.10 \$1.10 \$1.00 \$0.20		\$0.10			
Expiry Date	Nov. 27, 2015	Dec 23, 2015	Dec 23, 2015	Mar 13, 2016	Mar. 22, 2016	May 27, 2016	June 19, 2016	June 19, 2016
	#	#	#	#	#	#	#	#
Balance								
December 31, 2013	_	-	1,459,955	-	2,555,587	-	-	-
Issued	216,944	77,250	-	-	-	1,549,600	-	-
Exercised	-	-	-	-	-	-	-	-
Expired	-	-	-	-	-	-	-	-
Balance								
December 31, 2014	216,944	77,250	1,459,955	-	2,555,587	1,549,600	-	-
Issued	-	-	-	227,350	-	-	4,875,000	420,000
Exercised	-	-	-	-	-	-	-	-
Expired	-	-	-	-	-	-	-	-
Balance								
June 30, 2015	216,944	77,250	1,459,955	227,350	2,555,587	1,549,600	4,875,000	420,000

#### **Management's Discussion and Analysis**



#### Shareholder rights plan

The shareholders of the Company approved the adoption of a shareholder rights plan agreement (the "Plan") on September 22, 2011. The Plan is designed to provide adequate time for the Board of Directors and the shareholders to assess an unsolicited takeover bid for DiaMedica, to provide the Board of Directors with sufficient time to explore and develop alternatives for maximizing shareholder value if a takeover bid is made, and to provide shareholders with an equal opportunity to participate in a takeover bid and receive full and fair value for their Common Shares. The Plan had been set to expire at the close of the Company's annual meeting of shareholders in 2014. At the Company's Annual General and Special Meeting of Shareholders on July 24, 2014, shareholders approved a resolution to renew the Plan and extend the expiration date to the close of the Company's annual meeting of shareholders in 2017.

The rights issued under the Plan will initially attach to and trade with the Common Shares and no separate certificates will be issued unless an event triggering these rights occurs. The rights will become exercisable only when a person, including any party related to it, acquires or attempts to acquire 20 percent or more of the outstanding Common Shares without complying with the "Permitted Bid" provisions of the Plan or without approval of the Board of Directors. Should such an acquisition occur or be announced, each right would, upon exercise, entitle a rights holder, other than the acquiring person and related persons, to purchase Common Shares at a 50 percent discount to the market price at the time.

Under the Plan, a Permitted Bid is a bid made to all holders of the Common Shares and which is open for acceptance for not less than 60 days. If at the end of 60 days at least 50 percent of the outstanding Common Shares, other than those owned by the offeror and certain related parties have been tendered, the offeror may take up and pay for the Common Shares but must extend the bid for a further 10 days to allow other shareholders to tender. The issuance of Common Shares upon the exercise of the rights is subject to receipt of certain regulatory approvals.

#### **Deferred Share Units Plan**

The shareholders of the Company approved the adoption of a deferred share units plan (the "DSU Plan") on September 22, 2011 reserving for issuance up to 2,000,000 common shares under the DSU Plan. The purpose of the DSU Plan is to provide an alternative form of compensation for directors' fees and annual and special bonuses payable to senior officers and directors of the Corporation. For the six months ended June 30, 2015, no units were issued (2014 - no units issued) in the amount of nil (2014 - no). The DSU Plan is equity-settled and the fair value of units granted, which vest upon issuance, is included in share-based compensation expense.

#### **Commitments**

As at June 30, 2015 and in the normal course of business, the Company had obligations to make future payments, representing research and development contracts and other commitments that are known and committed in the amount of \$276,140 over the next 12 months. The Company's largest commitment is with the contract research organization running its Phase II clinical trial. As at June 30, 2015, the Company has future commitments totaling \$79,130 (€6,883) to this organization.

The Company enters into research, development and license agreements in the ordinary course of business where the Company receives research services and rights to proprietary technologies. Milestone and royalty payments that may become due under various agreements are dependent on, among other factors, clinical trials, regulatory approvals and ultimately the successful development of a new drug, the outcome and timing of which is uncertain.

The Company periodically enters into research and license agreements with third parties that include indemnification provisions customary in the industry. These guarantees generally require the Company to compensate the other party for certain damages and costs incurred as a result of claims arising from research and development activities undertaken by or on behalf of the Company. In some cases, the maximum potential amount of future payments that could be required under these indemnification provisions could be unlimited. These





indemnification provisions generally survive termination of the underlying agreement. The nature of the indemnification obligations prevents the Company from making a reasonable estimate of the maximum potential amount it could be required to pay. Historically, the Company has not made any indemnification payments under such agreements and no amount has been accrued in the accompanying consolidated financial statements with respect to these indemnification obligations.

#### RELATED PARTY TRANSACTIONS

The key management personnel of the Company are the Directors, the President and Chief Executive Officer, Chief Financial Officer and the Vice Presidents.

Compensation for key management personnel of the Company for the six months ended June 30, 2015 was as follows:

	2015	2014
	\$	\$
Salaries, fees and short-term benefits	290,895	572,784
Share-based compensation	(6,738)	197,658
Total personnel expenses	284,157	770,442

Executive officers and directors participate in the stock option plan and certain officers participate in the Company's health plan. Directors receive annual and meeting fees for their services. As at June 30, 2015, the key management personnel control approximately 4.3% (2014 – approximately 2%) of the voting shares of the Company.

Amounts due to related parties, including amounts due to key management personnel, at the year-end are unsecured, interest free and settlement occurs in cash. There have been no guarantees provided or received for any related party receivables or payables.

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

Other than as described above, the Company does not have any off-balance sheet arrangements.

#### INTERNAL CONTROLS OVER FINANCIAL REPORTING

As a result of the Company's limited administrative staffing levels, internal controls which rely on segregation of duties in many cases are not possible. Due to resource constraints and the present stage of the Company's development, the Company does not have sufficient size and scale to warrant the hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this, the Company is highly reliant on the performance of compensating procedures and senior management's review and approval. During the six months ended June 30, 2015, the Company appointed David Gurvey as Vice President of Finance in January 2015.

As a venture issuer, the Company is not required to certify the design and evaluation of the Company's disclosure controls and procedures ("DC&P") and internal controls over financial reporting ("ICFR"), and as such has not completed such an evaluation.

Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost effective basis DC&P and ICFR as defined in NI 52-109 may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

#### **Management's Discussion and Analysis**



#### CRITICAL ACCOUNTING ESTIMATES

The preparation of financial statements in conformity with IFRS requires the Company to select from possible alternative accounting principles and to make estimates and assumptions that determine the reported amounts of assets and liabilities at the balance sheet date, and reported costs and expenditures during the reporting period. Management believes that the estimates and assumptions upon which the Company relies are reasonable based upon information available at the time these estimates and assumptions are made. Estimates and assumptions may be revised as new information is acquired, and are subject to change. A summary of the Company's significant accounting policies and estimates under IFRS is found in Note 3 of the Company's consolidated financial statements for the year ended December 31, 2014.

In addition to the going concern assumptions described above, management believes that its most critical accounting policies and estimates relate to the following areas:

#### Valuation of share-based compensation and warrants

Management measures the costs for share-based compensation and warrants using market-based option valuation techniques. Assumptions are made and estimates are used in applying the valuation techniques. These include estimating the future volatility of the share price, expected dividend yield, expected risk-free interest rate, future employee turnover rates, future exercise behaviors and corporate performance. Such estimates and assumptions inherently are uncertain. Changes in these assumptions affect the fair value estimates of share-based payments and warrants.

#### Measurement, period of use and potential impairment of intangible assets

Management reviews objective evidence each reporting period to assess whether there are indications of impairment of the intangible assets and makes judgments about their period of use. These determinations and their individual assumptions require that management make a decision based on the best and most reliable information available at each reporting period.

#### **CHANGES IN ACCOUNTING POLICIES**

The Company's principal accounting policies are outlined in the Company's annual audited consolidated financial statements for the year ended December 31, 2014 and have been applied consistently to all periods presented in these consolidated financial statements, except as noted below. These statements should be read in conjunction with the annual audited consolidated financial statements for the year ended December 31, 2014.

#### New standards and interpretations not yet effective

#### IFRS 15, Revenue from Contracts with Customers

IFRS 15, Revenue from Contracts with Customers, issued by the IASB in May 2014, is applicable to all revenue contracts and provides a model for the recognition and measurement of gains or losses from sales of some non-financial assets. The core principle is that revenue is recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard will also result in enhanced disclosures about revenue, provide guidance for transactions that were not previously addressed comprehensively [for example, service revenue and contract modifications] and improve guidance for multiple-element arrangements. IFRS 15 is effective for annual periods beginning on or after January 1, 2017 and is to be applied retrospectively, with earlier adoption permitted. Entities will transition following either a full or modified retrospective approach. The Company is currently evaluating the impact of the above standard on its financial statements.

#### **Management's Discussion and Analysis**



Amendments to IAS 1, Presentation of Financial Statements

On December 18, 2014 the IASB issued amendments to IAS 1 as part of its major initiative to improve presentation and disclosure in financial reports (the "Disclosure Initiative"). The amendments are effective for annual period beginning on or after January 1, 2016. Early adoption is permitted. These amendments will not require any significant change to current practice, but should facilitate improved financial statement disclosures. The Company intends to adopt these amendments in its financial statements for the annual period beginning on January 1, 2016. The extent of the impact of adoption of the amendments has not yet been determined.

## SELECTED QUARTERLY FINANCIAL INFORMATION

The selected financial information provided below is derived from the Company's consolidated financial statements for each of the last eight quarters.

	Q2-2015	Q1-2015	Q4-2014	Q3-2014	Q2-2014		Q1-2014		Q4-2013		Q3-2013
Interest income	\$ 2,033	\$ 1,871	\$ 497	\$ 2,303	\$ 4,140	\$	5,291	\$	1,715	\$	4,738
Net loss for the period	\$ 978,624	\$ 562,104	\$ 1,053,721	\$ 983,977	\$ 1,307,737	\$2,	247,284	\$1	,483,301	\$1	,357,798
Loss per share	\$ (0.01)	\$ (0.01)	\$ (0.02)	\$ (0.02)	\$ (0.02)	\$	(0.04)	\$	(0.03)	\$	(0.02)
Cash and cash equivalents	\$ 568,759	\$ 339,627	\$ 236,567	\$ 542,984	\$ 1,332,701	\$1,	625,484	\$2	,684,498	\$1	,098,643

It is important to note that historical patterns of expenditures cannot be taken as an indication of future expenditures. The amount and timing of expenditures, and therefore liquidity and capital resources, may vary substantially from period to period depending on the business and research activities being undertaken at any one time and the availability of funding from investors and prospective commercial partners.

#### RISKS AND UNCERTAINTY

An investment in our common shares involves a high degree of risk and should be considered speculative. An investment in our common shares should only be undertaken by those persons who can afford the total loss of their investment. You should consider carefully the risks and uncertainties described below, as well as other information contained in this MD&A. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and you could lose all or part of your investment. Further, if we fail to meet the expectations of the public market in any given period, the market price of our common shares could decline.

We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control. We are subject to risks inherent in the biotechnology industry, including:

#### Risks Related to the Early Stage of our Products and our Company

Lack of Product Revenues; History of Operating Losses; Substantial Doubt about the Ability to Continue as a Going Concern

There is substantial doubt about the appropriateness of the use of the going concern assumption because we have experienced operating losses and cash outflows from operations since incorporation, we had a working capital deficiency as of June 30, 2015, our cash resources are not sufficient for the next twelve months of planned operations, and we have not reached successful commercialization of our products. As of the date of this MD&A, we have not recorded any revenues from the sale of products. We have an accumulated deficit, based on our consolidated financial statements, since our inception through June 30, 2015 of over \$46.1 million. Operating losses

#### **Management's Discussion and Analysis**



are expected to increase in the near term as we continue our product development efforts and are expected to continue until such time as product sales, royalty payments, licensing fees and/or milestone payments are sufficient to generate revenues to fund our continuing operations. We are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

The Company's future operations are dependent upon its ability to secure additional funds. While the Company is taking measures to preserve cash while it continues to search for additional sources of funding, the Company will not have enough cash on hand to sustain operations beyond the end of June 2015 unless further funds have been raised. During the fourth quarter and subsequent, management has implemented various plans to reduce cash outflows, including a reduction in pay for employees, elimination of certain positions and the voluntary waiving of payments of director fees by the Directors of the Company. In addition, the Company is in discussions with vendors to reduce, restructure and/or defer or extend past due payments to reduce cash outflows and improve liquidity until additional funds have been raised. The success of management's planned initiatives and actions referred to above cannot be assured, and may be subject to material change or revision at any time. Further, there can be no assurance that the Company will be successful in raising additional capital on favorable terms or at all. The availability of financing will be affected by the results of scientific and clinical research, the ability to attain regulatory approvals, the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies and other relevant commercial considerations. If the Company cannot secure additional financing on favorable terms or at all, the Company will have to consider additional strategic alternatives beyond the cost saving measures described above. Such additional strategies may include delays of product development expenditures, exploring the monetization of certain intangible assets, as well as seeking to out-license and/or divest assets through a merger, sale or liquidation of the Company.

The ability of the Company to continue as a going concern and to realize the carrying value of its assets and settle its liabilities and commitments when due is dependent on many factors, including, but not limited to the successful completion of the actions taken or planned, some of which are described above, which are intended to mitigate the adverse conditions and events which raise substantial doubt about the validity of the going concern assumption used in preparing these consolidated financial statements. There can be no assurance that the Company will be able to obtain sufficient financing to meet future operational needs or that the above described and other strategies will be sufficient to permit the Company to continue as a going concern.

#### Stage of Development

We have compounds in various stages of development. Prior to commercialization of any potential product, significant additional investments will be necessary to complete the development of any of our products. Preclinical and clinical trial work must be completed before some of our other products could be ready for use within the market that we have identified. We may fail to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. Competitors may develop alternative products and methodologies to treat and diagnose the disease indications we are pursuing, thus reducing our competitive advantages. We do not know whether any of our potential product development efforts will prove to be effective, meet applicable regulatory standards, obtain the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or successfully marketed. The products or processes we are currently developing are not expected to be commercially viable for several years and we may encounter unforeseen difficulties or delays in commercializing our products. In addition, our products may cause undesirable side effects. Results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research, including replicating positive human efficacy results of urinary KLK1 with DM199. If regulatory authorities do not approve our products or if we fail to maintain regulatory compliance, we would have limited ability to commercialize our products, and our business and results of operations would be harmed. If we do succeed in developing products, we will face many potential obstacles such as the need to develop or obtain manufacturing, marketing and distribution capabilities.

#### **Management's Discussion and Analysis**



#### **Risks and Uncertainties of Current Economic Conditions**

To date, we have primarily relied on equity financing to fund our working capital requirements and drug development activities. A substantial amount of additional capital is needed to develop our products to a point where they may be commercially sold. Our future operations are dependent upon our ability to generate product sales, negotiate collaboration or license agreements, obtain research grant funding, defer expenditures, or other strategic alternatives, and/or secure additional funds. While we are striving to achieve these plans, there is no assurance these and other strategies will be achieved or that such sources of funds will be available or obtained on favorable terms or obtained at all. Our ability to continue as a going concern is dependent on our ability to continue obtaining sufficient funds to conduct our research and development, and to successfully commercialize our products. See Liquidity and Capital Resources section below.

#### Risks Related to our Business and our Industry

#### Uncertainties Related to Clinical Trials and Product Development

Before obtaining regulatory clearance for the commercial sale of any of our products under development, we must demonstrate through preclinical studies and clinical trials that the potential product is safe and efficacious for use in humans for each target indication. The results from preclinical studies and early clinical trials may not be predictive of results that will be obtained in large clinical trials, and there can be no assurance that our clinical trials will demonstrate sufficient safety and efficacy necessary to obtain the requisite regulatory approvals or will result in marketable products. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The failure to adequately demonstrate the safety and efficacy of a product under development could delay or prevent regulatory clearance of the potential product and would have a material adverse effect on our success. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for sufficiently long periods of time. There can be no assurance that unacceptable toxicity or side effects will not occur at any dose level at any time in the course of human clinical trials of our potential products. The appearance of any such unacceptable toxicity or side effects in clinical trials could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our product candidates and could ultimately prevent their clearance by the United States Food and Drug Administration ("FDA") or other regulatory authorities, for any or all targeted indications. Even after being cleared by the FDA or other regulatory authorities, a product may later be shown to be unsafe or not to have its purported effect, thereby preventing its widespread use or requiring withdrawal from the market. There can be no assurance that any of our products or product candidates will be safe when administered to patients.

The rate of completion of our clinical trials will be dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of parties to clinical sites and the eligibility criteria for the study. Delays in planned patient enrollment may result in increased costs, delays or termination of clinical trials, which could have a material adverse effect on our success.

In addition, we rely on third parties to assist us in overseeing and monitoring the clinical trials, which may result in delays in completing clinical trials, or the trials not being completed at all, if such third parties fail to perform under their agreements with us or fail to meet regulatory standards in the performance of their obligations under such agreements. There can be no assurance that we will be able to submit a new drug application as scheduled if clinical trials are completed or that any such applications will be reviewed and cleared by the FDA or other regulatory authority in a timely manner or at all.

#### **Risks Related to Regulatory Matters**

#### Management's Discussion and Analysis



Potential investors should be aware of the risks, problems, delays, expenses and difficulties which we may encounter in light of the extensive regulatory environment within which our business is carried out. Numerous statutes and regulations govern the manufacture and sale of non-therapeutic and human therapeutic products in the United States, Canada and other countries that are the intended markets for our products and product candidates. Such legislation and regulation governs the approval of manufacturing facilities, the testing procedures and controlled research that must be carried out and the preclinical and clinical data that must be collected prior to marketing approval. Our research and development efforts, as well as any future clinical trials, and the manufacturing and marketing of any products we may develop, will be subject to and restricted by such extensive regulation.

The process of obtaining necessary regulatory approvals is lengthy, expensive and uncertain. We or our collaborators may fail to obtain the necessary approvals to commence or continue clinical testing or to manufacture or market our potential products in reasonable time frames, if at all. In addition, governmental authorities in the United States, or other countries may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect the regulatory environment in which we operate or the development of any products we may develop.

Completing clinical testing and obtaining required approvals is expected to take several years and to require the expenditure of substantial resources. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials may be delayed or suspended at any time by us or by the various regulatory authorities if it is determined at any time that the subjects or patients are being exposed to unacceptable risks.

Any failure or delay in obtaining regulatory approvals would adversely affect our ability to utilize our technology and would therefore adversely affect our operations. Furthermore, no assurance can be given that our product candidates will prove to be safe and effective in clinical trials or that they will receive the requisite regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may be granted with specific limitations on the indicated uses for which that drug may be marketed. Furthermore, product approvals may be withdrawn if problems occur following initial marketing or if compliance with regulatory standards is not maintained.

In addition, we rely to some extent on the availability of certain agents that are currently marketed by other firms. Such agents may become unavailable as a result of failing to meet regulatory requirements.

#### **Additional Financing Requirements and Access to Capital**

We require significant additional funds for further research and development, planned clinical trials, and the regulatory approval process. We may raise additional funds for the aforementioned purposes through public or private equity or debt financing which may be dilutive, or through collaborations with other biotechnology companies, or financing from other sources may be undertaken. It is possible that financing will not be available or, if available, may not be on favorable terms. The availability of financing will be affected by the results of scientific and clinical research, the ability to attain regulatory approvals, market acceptance of our products, the state of the capital markets generally with particular reference to pharmaceutical, biotechnology and medical companies, the status of strategic alliance agreements, and other relevant commercial considerations. If adequate funding is not available, we may be required to implement more aggressive cost reduction strategies than those currently contemplated; delay, reduce, or eliminate one or more of our product development programs; relinquish significant rights to product candidates or obtain funds on less favorable terms than we would otherwise accept; and/or divest assets through a merger, sale or liquidation of the Company.

#### Rapid Technological Change

The industry in which we operate is characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render our products or technologies non- competitive or that we will be able to keep pace with technological developments. Our competitors may have developed or may be developing

#### **Management's Discussion and Analysis**



technologies which could become the basis for competitive products. Some of these products may prove to be more effective and less costly than our products.

#### Partnerships for Development and Commercialization of Technology

We may need, but be unable, to obtain partners to support our development efforts and to commercialize our technology. Equity and/or debt financings alone may not be sufficient to fund the cost of developing our products, and we may need to rely on our ability to reach partnering arrangements to provide financial support for our discovery and development efforts.

In addition, in order to successfully develop and commercialize our technology, we may need to enter into a wide variety of arrangements with corporate sponsors, pharmaceutical companies, universities, research groups and others. While we have had previous research contracts, we may enter into additional arrangements with other contract research organizations. We may fail to obtain any such agreements on terms acceptable to us or at all. Even if we enter into these arrangements, we may not be able to satisfy our obligations under them or renew or replace them after their original terms expire. Furthermore, arrangements of this nature may require us to grant certain rights to third parties, including exclusive marketing rights to one or more products, may require us to issue securities to our collaborators or may contain other terms that are burdensome to us. If any of our collaborators terminate their relationship with us or fail to perform their obligations in a timely manner, the development or commercialization of our technology and potential products may be adversely affected.

#### Clinical Trials Outside of the United States

Our recently completed Phase I/II clinical trials of DM199 in patients with T2D was conducted in the Netherlands with PRA International under EMA regulatory authority. We may conduct future clinical trials outside of the United States. While any such study would be conducted in accordance with international regulatory standards including compliance with Good Clinical Practice ("GCP") regulations and International Committee on Harmonization ("ICH") guidelines, there is a risk that the FDA may not accept the results in support of filing an Investigational New Drug ("IND") application.

#### **Uncertainties Related to Forecasts**

Our expectations regarding the success of our product candidates and our business are based on forecasts which may include the commencement and completion of clinical trials and anticipated regulatory approval which may not be realized. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing capacity and marketing infrastructure sufficient to commercialize our biopharmaceutical products. There can be no assurance that clinical trials involving our products will be successfully completed, that we will make regulatory submissions or receive regulatory approvals as forecasted or that we will be able to adhere to our current schedule. The failure to do so could have a material adverse effect on us.

#### **Competition**

Technological competition is intense in the industry in which we operate. Competition comes from pharmaceutical companies, biotechnology companies and universities as well as companies that participate in each of the non-pharmaceutical markets we may attempt to address with our products. Many of our competitors have substantially greater financial and technical resources, more extensive research and development capabilities and greater marketing, distribution, production and human resources than we do. Moreover, competitors may develop products more quickly than us and may obtain regulatory approval for such products more rapidly than we do. Products and processes which are more effective than those that we intend to develop may be developed by our competitors. Research and development by others may render our technology products or processes non-competitive or obsolete.

#### **Management's Discussion and Analysis**



#### Unproven Market

Notwithstanding the estimated market potential for our products and product candidates, no assurance can be given that our projections and assumptions will prove to be correct owing to, in particular, competition from existing or new products and the yet to be established clinical viability of our identified drug candidates.

#### Management of Growth

Engagement of a clinical trial and future pipeline development has placed, and is expected to continue to place, a significant strain on our managerial, operational and technical resources. We expect operating expenses and staffing levels to increase in the future. To manage our growth, we must expand our operational and technical capabilities and our employee base while effectively administering multiple relationships with various third parties. There can be no assurance that we will be able to manage our expanding operations effectively. Any failure to implement cohesive management and operating systems, add resources on a cost-effective basis or properly manage our expansion could have a material adverse effect on our business and results of operations.

#### Dependence on Key Personnel

We depend on our management personnel. However, in light of our current financial condition we recently implemented an immediate reduction in pay for all employees and eliminated certain positions. Further cost saving measures in the form of deeper pay cuts and/or additional reductions in staff may be necessary. The loss of services of one or more of such persons could adversely affect our operations. Further, no assurance can be given that we will be able to attract and retain skilled and experienced personnel.

#### Supply of Raw Materials

We have selected manufacturers that we believe comply with Current Good Manufacturing Practices, ("cGMP") and other applicable regulatory standards. Although the manufacturers are experienced, no assurance can be given that sufficient quantities for on-going studies and for future clinical trials will be produced, or produced on terms that are acceptable to us.

#### Systems Failures

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug discovery programs. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability as a result, our drug discovery programs may be adversely affected and the further development of our product candidates may be delayed. In addition, we may incur additional costs to remedy the damages caused by these disruptions or security breaches.

#### Effect of Insurers' Willingness to Pay for Products and Our Ability to Become Profitable

Since health care insurers and other organizations may not pay for any products that we may develop or may impose limits on reimbursements, our ability to become profitable could be reduced. In both domestic and foreign markets, sales of potential products are likely to depend in part upon the availability and amounts of reimbursement from third party health care payor organizations, including government agencies, private health care insurers and other health care payors, such as health maintenance organizations and self-insured employee plans. There is considerable pressure to reduce the cost of therapeutic products, and government and other third party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products and by refusing, in some cases, to provide any coverage for uses of approved products for disease

#### **Management's Discussion and Analysis**



indications for which marketing approval has not been granted. Significant uncertainty exists as to the reimbursement status of newly approved health care products or novel therapies. We can give no assurance that reimbursement will be provided by such payors at all or without substantial delay or, if such reimbursement is provided, that the approved reimbursement amounts will be sufficient to enable us to sell products we may develop on a profitable basis. Changes in reimbursement policies could also adversely affect the willingness of pharmaceutical companies to collaborate with us on the development of our product candidates. In certain markets, pricing or profitability of prescription pharmaceuticals is subject to government control.

#### Potential Product Liability

A risk of product liability claims and related negative publicity is inherent in the development of human therapeutics and other products. Product liability insurance is expensive, its availability is limited, and it may not be offered on terms acceptable to us, if at all. The commercialization of our potential products could be inhibited or prevented by an inability to maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims. A product liability claim against us or the withdrawal of a product from the market could have a material adverse effect upon us and our financial condition. To protect against potential product liability risks, we have €450,000 per occurrence, €3.5 million clinical trial insurance and US\$5.0 million product liability insurance coverage.

#### Foreign Currency Risk

A portion of our expenditures are in US dollars and euros and, therefore, we are subject to foreign currency fluctuations which may, from time to time, impact our financial position and results of operations.

#### Patents and Proprietary Rights

We believe that patents and other proprietary rights are important to our business. Our policy is to file patent applications to protect technology, inventions and improvements that may be important to the development of our business. We also rely upon trade secrets, know-how, continuing technological innovations and licensing opportunities to develop and maintain our competitive position. We plan to enforce our issued patents and our rights to proprietary information and technology. We review third- party patents and patent applications, both to refine our own patent strategy and to identify useful licensing opportunities.

Our success depends, in part, on our ability to secure and protect our intellectual property rights and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us. We have a number of patents, patent applications and rights to patents related to our compounds, products and technology, but we cannot be certain that they will be enforceable or provide adequate protection or that pending patent applications will result in issued patents.

To the extent that development, manufacturing and testing of our products is performed by third party contractors, such work is performed pursuant to fee for service contracts. Under the contracts, all intellectual property, technology know-how and trade secrets arising under such agreements are our exclusive property, and must be kept confidential by the contractors. It is not possible for us to be certain that we have obtained from the contractors all necessary rights to such technologies. Disputes may arise as to the scope of the contract, or possible breach of contract. No assurance can be given that our contracts would be enforceable or would be upheld by a court.

The patent positions of pharmaceutical and biotechnology firms, ourselves included, are uncertain and involve complex questions of law and fact for which important legal issues remain unresolved. Therefore, it is not clear whether our pending patent applications will result in the issuance of patents or whether we will develop additional proprietary products which are patentable. Part of our strategy is based on our ability to secure a patent position to protect our technology. There is no assurance that we will be successful in this approach and failure to secure patent protection may have a material adverse effect upon us and our financial condition. Also, we may fail in our attempt to commercialize products using currently patented or licensed technology without having to license additional

## Management's Discussion and Analysis



patents. Moreover, it is not clear whether the patents issued or to be issued will provide us with any competitive advantages or if any such patents will be the target of challenges by third parties, whether the patents of others will interfere with our ability to market our products or whether third parties will circumvent our patents by means of alternate processes. Furthermore, it is possible for others to develop products which have the same effect as our products or technologies on an independent basis or to design around technologies patented by us. Patent applications relating to or affecting our business may have been filed by pharmaceutical or biotechnology companies or academic institutions. Such applications may conflict with our technologies or patent applications and such conflict could reduce the scope of patent protection which we could otherwise obtain or even lead to the rejection of our patent applications. There is no assurance that we can enter into licensing arrangements on reasonable commercial terms, or develop or obtain alternative technology in respect of patents issued to third parties that incidentally cover our products or production technologies. Any inability to secure licenses or alternative technology could result in delays in the introduction of some of our products or even lead to us being prevented from pursuing the development, manufacture or sale of certain products. Moreover, we could potentially incur substantial legal costs in defending legal actions which allege patent infringement, or by initiating patent infringement suits against others. It is not possible for us to be certain that we are the creator of inventions covered by pending patent applications or that we were the first to invent or file patent applications for any such inventions. While we have used commercially reasonable efforts to obtain assignments of intellectual property from all individuals who may have created materials on our behalf (including with respect to inventions covered by our patent and pending patent applications), it is not possible for us to be certain that we have obtained all necessary rights to such materials. No assurance can be given that our patents, if issued, would be upheld by a court, or that a competitor's technology or product would be found to infringe on our patents. Moreover, much of our technology know-how that is not patentable may constitute trade secrets. Therefore, we require our employees, consultants, advisors and collaborators to enter into confidentiality agreements either as stand-alone agreements or as part of their consulting contracts. However, no assurance can be given that such agreements will provide meaningful protection of our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure of confidential information. Also, while we have used commercially reasonable efforts to obtain executed copies of such agreements from all employees, consultants, advisors and collaborators, no assurance can be given that executed copies of all such agreements have been obtained.

#### Costs Stemming from Defense Against Third-Party Intellectual Property Infringement Claims

Third parties may claim that we are using their proprietary information without authorization. Third parties may also have or obtain patents and may claim that technologies licensed to or used by us infringe their patents. If we are required to defend patent infringement actions brought by third parties, or if we sue to protect our own patent rights or otherwise to protect our proprietary information and to prevent its disclosure, we may be required to pay substantial litigation costs and managerial attention may be diverted from business operations even if the outcome is in our favor. In addition, any legal action that seeks damages or an injunction to stop us from carrying on our commercial activities relating to the affected technologies could subject us to monetary liability and require us or any third party licensors to obtain a license to continue to use the affected technologies. We cannot predict whether we would prevail in any of these types of actions or that any required license would be available on commercially acceptable terms or at all. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources.

#### Risks Related to the Company's Common Shares

#### Share Price Volatility

A number of factors could influence the volatility in the trading price of our common shares, including changes in the economy or in the financial markets, industry related developments, and the impact of material events and changes in our operations. Our quarterly losses may vary because of expenses we incur related to future research including the timing of costs for manufacturing and initiating and completing preclinical and clinical trials. Each of these factors could lead to increased volatility in the market price of our common shares. In addition, the market prices of the securities of our competitors may also lead to fluctuations in the trading price of our common shares.

## **Management's Discussion and Analysis**



#### Dividends

We have not declared or paid any cash dividends on our common shares to date. The payment of dividends in the future will be dependent on our earnings and financial condition and on such other factors as our board of directors considers appropriate. Unless and until we pay dividends, shareholders may not receive a return on their shares. There is no present intention by our board of directors to pay dividends on our common shares.

#### Dilution

You may experience future dilution due to additional future equity financing events by the Company. If outstanding options, warrants or deferred share units of the Company are exercised into common shares, you will experience additional dilution.

## **Additional Information**

Additional information relating to the Company, including its Annual Information Form can be found on SEDAR at www.sedar.com.