March 10, 2021

DiaMedica Therapeutics Announces 2020 Financial Results and Provides a Business Update

- ***Productive Type B Pre-IND Meeting with FDA Provides Clarity for Planned Stroke Study Program***
- ***On Track to Initiate Phase 2/3 AIS Trial in Summer 2021***
- ***REDUX Phase 2 Diabetic Kidney Disease Cohort Readout Expected in Q2 2021***
- ***ReMEDy Phase 2 AIS Study Data to be Presented at the 2021 International Stroke Conference***
- ***Stroke KOL Webinar Discussing the Treatment of Acute Ischemic Stroke on March 19th***
- ***Cash Runway Through Mid-2022***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and kidney diseases, today provided a business update and financial results for the year ended December 31, 2020. DiaMedica will host a conference call Thursday, March 11, 2021, at 7:00 a.m. Central Time to discuss its business update and full year financial results.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

Productive Type B Meeting with the FDA

Initiation of Phase 2/3 Trial in AIS

The U.S. Food and Drug Administration (FDA) accepted DiaMedica's request for a Type B Pre-IND meeting request related to its development plan for its product candidate, DM199, in the treatment of acute ischemic stroke (AIS). In written responses to the questions submitted by DiaMedica, the FDA agreed with DiaMedica's proposals regarding key elements of a Phase 2/3 trial for DM199 in patients with AIS. These plans include an adaptive trial design with a primary endpoint based upon the modified Rankin Scale (mRS) at day 90.

The FDA also acknowledged that, provided the study results qualify, a single trial may support a Biologics License Application (BLA) submission. Additionally, based upon the clinical and preclinical testing performed to date and currently in process, the FDA did not require any additional studies in preparation for an investigational new drug (IND) submission and initiation of the Company's planned Phase 2/3 trial.

DiaMedica believes that the feedback received from the FDA provided a well-defined

regulatory pathway and is proceeding with the preparation of an IND submission to initiate a Phase 2/3 adaptive trial design which will include an interim analysis to allow for an increase in the sample size, if necessary, to improve powering.

DiaMedica plans to submit the IND later this month for its proposed Phase 2/3 AIS trial and initiate it this summer. DiaMedica expects the trial will be a double blinded, placebo controlled, randomized study of approximately 350 participants, based on a 90% powering for statistical significance on the primary endpoint of mRS at day 90. Secondary endpoints will include stroke recurrence, mRS shift, NIHSS and Barthel Index, deaths, safety and tolerability measures, and biomarkers relating to KLK1. The Company also plans to discuss with the FDA the addition of a sub-study for proof of efficacy in reducing stroke recurrence based upon the statistically significant reduction in severe recurrent strokes observed in its ReMEDy Phase 2 AIS trial.

The results of the Company's ReMEDy Phase 2 trial in AIS will be the subject of oral and poster presentations at the upcoming International Stroke Conference 2021 being held virtually on March 17-19, 2021.

The Company will also be hosting a Stroke KOL webinar on the Treatment of Acute Ischemic Stroke on March 19th at noon Eastern Time. To register for the webinar, please click here.

"We are very pleased with the progress we've made in recent weeks advancing our DM199 program for AIS patients," said Rick Pauls, President and Chief Executive Officer of DiaMedica. "Our Phase 2/3 trial builds on statistically and clinically significant results from our ReMEDy trial, and we're committed to designing and executing a study that meets the qualifications for and could provide evidence to support a BLA submission."

DM199 for the Treatment of Chronic Kidney Disease

> *Completion of Enrollment in CKD Caused by Type II Diabetes Cohort; Data Read-out in Q2 2021*
>
> *Enrollment Continues in IgA Nephropathy and CKD in African Americans with Hypertension*

DiaMedica's Phase 2 REDUX (Latin for restore) trial is a multi-center, open-label, investigation to assess the safety and efficacy of multiple doses of DM199, administered over 90 days, in participants with chronic kidney disease (CKD) (Stage 2 or 3) targeting enrollment of approximately 90 participants in three equal Cohorts. Cohort 1 of the study is focused on non-diabetic, African Americans with hypertension, a group that is at greater risk for CKD than Caucasians. Additionally, the study is designed to identify African American participants with the APOL1 gene mutation as an exploratory biomarker as these individuals have an even higher risk of developing CKD. Cohort 2 of the study is focused on participants with IgA Nephropathy (IgAN) and Cohort 3 includes participants with diabetic kidney disease (DKD).

As of March 1, 2020, DiaMedica had enrolled a total of 68 subjects, including a fully enrolled DKD Cohort, and approximately 70% of the IgAN and 50% of the African American Cohorts. The Company has continued to experience slower than expected enrollment in the first two

Cohorts of the REDUX trial due to the COVID-19 pandemic. However, with the significant declines in new COVID-19 cases and the anticipated availability and effectiveness of vaccines, the Company currently anticipates completion of Cohort 1 and Cohort 2 in the second half of 2021. Preliminary topline results from the DKD Cohort are expected to be available in the second quarter of 2021.

“We look forward to reporting upcoming topline results from our Phase 2 REDUX trial,” commented Dr. Harry Alcorn, Jr., DiaMedica’s Chief Medical Officer. “While we intend to follow the data from all three Cohorts, we anticipate that for CKD, we will have the opportunity to initially position D199 in patients with IgA Nephropathy, an orphan drug indication, and in the longer term provide a treatment option to the overall CKD and DKD patient populations.”

Strengthening the Balance Sheet

During 2020, the Company completed two underwritten public offerings of its common shares receiving gross proceeds of $31.5 million, and net proceeds of $28.8 million, after deducting the underwriting discount and estimated offering expenses. DiaMedica ended 2020 with $27.5 million in cash, cash equivalents and marketable securities which should provide sufficient capital to fund the Company's operations through mid-2022 and which the Company believes will allow it to complete the REDUX trial and initiate its Phase 2/3 trial in AIS.

Financial Results

Research and development (R&D) expenses were $8.3 million for the year ended December 31, 2020 compared to $7.9 million for the year ended December 31, 2019, an increase of $0.4 million. The increase was primarily due to a combination of costs incurred for the REDUX Phase 2 CKD study initiated late in 2019, driven in particular by the addition of Cohort 3 targeting participants with DKD, which fully enrolled during the fourth quarter of 2020, and increased non-cash share-based compensation costs. These increases were partially offset by decreases in clinical study costs incurred for the ReMEDy stroke study, which wound down in the first half of 2020, and non-recurring costs of the Phase 1b CKD study which was started and completed in the prior year period. Additionally, there was a year over year net decrease in drug manufacturing and development costs.

General and administrative (G&A) expenses were $4.4 million and $3.7 million for the years ended December 31, 2020 and 2019, respectively. This $0.7 million increase was primarily due to increased non-cash share-based compensation costs, outside professional services and directors and officers’ liability insurance. The increase in 2020 was partially offset by reduced travel and meeting costs primarily due to the COVID-19 pandemic.

Total other income, net was $0.4 million for the year ended December 31, 2020 compared to $1.0 million for 2019. This decrease was driven primarily by reduced R&D incentives receivable from the Australian Government, paid for qualifying research work performed by DiaMedica’s Australian subsidiary during 2020, related to the decreased ReMEDy stroke study costs. This decrease was partially offset by increased foreign currency transaction gains recognized during 2020.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of $27.5 million, current liabilities of $2.0 million and working capital of $25.9 million as of December 31, 2020, compared to $7.9 million in cash, cash equivalents and marketable securities, $1.3 million in current liabilities and $7.5 million in working capital as of December 31, 2019. The increases in the Company's combined cash, cash equivalents and marketable securities and in its working capital are due primarily to the Company's February and August 2020 public offerings.

Net cash used in operating activities was $9.2 million for the year ended December 31, 2020, compared to $9.1 million for the year ended December 31, 2019. This slight increase relates primarily to the combination of the increase in the net loss, partially offset by an increase in non-cash share-based compensation.

Conference Call Information

DiaMedica Management will host a conference call to discuss its 2020 financial results and business update on Thursday, March 11 2021, at 7:00 a.m. Central Time:

Date:	Thursday, March 11, 2021
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://event.on24.com/wcc/r/2948450/3CC8FC74172F3DEDB9258000144DA5E4
Dial In:	(866) 393-4306 (domestic)
	(734) 385-2616 (international)
Conference ID:	9297319

Interested parties may access the conference call by dialing in or listening to the simultaneous webcast. Listeners should log on to the website or dial in 15 minutes prior to the call. The webcast will remain available for play back on DiaMedica's website, under investor events and presentations, following the earnings call and for 12 months thereafter. A telephonic replay of the conference call will be available until March 18, 2021, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), replay passcode 9297319.

About DM199

DM199 is a recombinant (synthetic) form of human tissue kallikrein-1 (KLK1). KLK1 is a serine protease (protein) that plays an important role in the regulation of diverse physiological processes including blood flow, inflammation, fibrosis, oxidative stress and neurogenesis via a molecular mechanism that increases production of nitric oxide and prostaglandin. KLK1 deficiency may play a role in multiple vascular and fibrotic diseases such as chronic kidney disease, retinopathy, stroke, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed a recombinant form of the KLK1 protein. The KLK1 protein, produced from porcine pancreas and human urine, has been used to treat patients in Japan, China and Korea for decades. DM199 is currently being studied in patients with chronic kidney disease and patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. (Nasdaq: DMAC) is a clinical stage biopharmaceutical company focused on developing novel treatments to improve the lives of patients with neurological and chronic kidney diseases. To learn more about DiaMedica, visit

www.diamedica.com.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and forward-looking information that are based on the beliefs of management and reflect management's current expectations. When used in this press release, the words "estimate," "believe," "anticipate," "intend," "expect," "plan," "continue," "look forward," "will," "may" or "should," the negative of these words or such variations thereon or comparable terminology and the use of future dates are intended to identify forward-looking statements and information. The forward-looking statements and information in this press release include statements regarding the anticipated clinical benefits and success of DM199, the timing and requirements of its clinical programs, including its anticipated Phase 2/3 trial for DM199 in patients with AIS, and enrollment, clinical results and ability to achieve clinical milestones, including completion of enrollment and readout of results in its REDUX trial, its opportunity to initially position D199 in patients with IgA Nephropathy and in the longer term provide a treatment option to the overall CKD and DKD patient populations, and cash runway timing. Such statements and information reflect management's current view and DiaMedica undertakes no obligation to update or revise any of these statements or information. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements, or other future events, to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Applicable risks and uncertainties include, among others, the possibility of unfavorable results from DiaMedica's ongoing or future clinical trials of DM199; the risk that existing preclinical and clinical data may not be predictive of the results of ongoing or later clinical trials; DiaMedica's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of AIS and CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on DiaMedica's business; DiaMedica's reliance on collaboration with third parties to conduct clinical trials; DiaMedica's ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for AIS and CKD, and the risks identified under the heading "Risk Factors" in DiaMedica's annual report on Form 10-K for the fiscal year ended December 31, 2020. The forward-looking information contained in this press release represents the expectations of DiaMedica as of the date of this press release and, accordingly, is subject to change after such date. Readers should not place undue importance on forward-looking information and should not rely upon this information as of any other date. While DiaMedica may elect to, it does not undertake to update this information at any particular time except as required in accordance with applicable laws.

DiaMedica Therapeutics Inc.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development	8,310	7,900
General and administrative	4,389	3,693
Operating loss	(12,699)	(11,593)
Other (income) expense:		
Governmental assistance - research incentives	(205)	(856)
Other income, net	(229)	(119)
Total other income, net	(434)	(975)
Loss before income tax expense	(12,265)	(10,618)
Income tax expense	27	31
Net loss	(12,292)	(10,649)
Other comprehensive (income) loss		
Unrealized (gain) loss on marketable securities	4	(2)
Net loss and comprehensive loss	$ (12,296)	$ (10,647)
Basic and diluted net loss per share	$ (0.78)	$ (0.89)
Weighted average shares outstanding – basic and diluted	15,680,320	11,987,696

DiaMedica Therapeutics Inc.
Consolidated Balance Sheets
(In thousands, except share amounts)

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,409	$ 3,883
Marketable securities	20,098	3,995
Amounts receivable	340	823
Prepaid expenses and other assets	64	47
Deposits	10	88
Total current assets	27,921	8,836
Non-current assets:		
Operating lease right-of-use asset	100	153
Property and equipment, net	74	64
Total non-current assets	174	217
Total assets	$ 28,095	$ 9,053
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,099	$ 182
Accrued liabilities	864	1,076
Finance lease obligation	6	6
Operating lease obligation	59	54
Total current liabilities	2,028	1,318
Non-current liabilities:		
Finance lease obligation, non-current	7	13
Operating lease obligation, non-current	46	105
Total non-current liabilities	53	118
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,746,157 and 12,006,874 shares issued and outstanding, as of September 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	94,925	64,232
Accumulated other comprehensive income	(2)	2
Accumulated deficit	(68,909)	(56,617)
Total shareholders' equity	26,014	7,617
Total liabilities and shareholders' equity	$ 28,095	$ 9,053

DiaMedica Therapeutics Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (12,292)	$ (10,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,843	1,164
Amortization of discount on marketable securities	(4)	(74)
Non-cash lease expense	52	49
Depreciation	21	21
Changes in operating assets and liabilities:		
Amounts receivable	483	(43)
Prepaid expenses	(17)	322
Deposits	78	183
Accounts payable	917	(301)
Accrued liabilities	(266)	226
Net cash used in operating activities	(9,185)	(9,102)
Cash flows from investing activities:		
Purchase of marketable securities	(39,746)	(12,919)
Maturities of marketable securities	23,643	9,000
Purchase of property and equipment	(47)	(2)
Disposition of property and equipment, net	16	13
Net cash used in investing activities	(16,134)	(3,908)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	28,805	—
Proceeds from the exercise of stock options	45	75
Principal payments on finance lease obligations	(5)	(5)
Net cash provided by financing activities	28,845	70
Net increase (decrease) in cash and cash equivalents	3,526	(12,940)
Cash and cash equivalents at beginning of period	3,883	16,823
Cash and cash equivalents at end of period	$ 7,409	$ 3,883

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