May 13, 2020

DiaMedica Announces Positive Results in Top-Line Data from the Phase II ReMEDy Acute Ischemic Stroke Study and Provides a Business Update and First Quarter 2020 Financial Results

- ***DM199 Met Primary Safety and Tolerability Endpoints in ReMEDy Study Top-Line Data***
- ***Demonstrated Therapeutic Effect in Patients Not Pre-treated with Mechanical Thrombectomy***
- ***DiaMedica Completes $8.5M Public Offering of Common Shares***
- ***Cash and Investments of $12.6 Million; Runway Through 2021***
- ***Conference Call with Management Tomorrow, May 14 at 7am CT***

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for kidney diseases and neurological disorders, today announced positive top-line results from ReMEDy, its Phase II study in acute ischemic stroke (AIS), as well as provided a business update and financial results for the three months ended March 31, 2020. DiaMedica will host a conference call with slides tomorrow, May 14, 2020, at 7:00 a.m. Central Time to discuss its ReMEDy top-line data, business update and first quarter financial results. In conjunction with this release, DiaMedica also issued today a separate more detailed release on the ReMEDy top-line data.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

DM199 Acute Ischemic Stroke Phase II "ReMEDy" Trial – Positive Top-Line Data

DiaMedica today announced positive top-line results from its ReMEDy trial, a Phase II study assessing the safety, tolerability and therapeutic potential of DM199 in participants suffering from AIS. Final enrollment was 92 participants. The markers of therapeutic efficacy included the National Institutes of Health Stroke Scale, Modified Rankin Scale and the Barthel Index and multiple plasma-based biomarkers (e.g. C-reactive protein). These markers were assessed at multiple points throughout the study, including 90 days post-stroke.

DM199 met primary safety and tolerability endpoints and no DM199-related serious adverse events were noted in the study. According to top-line phase II results, there was also a demonstrated therapeutic effect in participants who received tissue plasminogen activator (tPA) prior to enrollment, but not in participants receiving mechanical thrombectomy.

"We are very excited about the positive top-line results which continue to demonstrate the excellent safety profile of DM199 and efficacy signals which are consistent with the approval study for Kailikang®, the urine-derived form of KLK1 which has been used to successfully treat stroke patients in China for years," stated Rick Pauls, DiaMedica's President and CEO. "These results strengthen our belief that DM199 can be a valuable treatment option for stroke victims, improving outcomes while providing a significantly longer, up to 24 hours, after onset of the stroke. We look forward to discussing a path to commercialization with the FDA."

DM199 for the Treatment of Chronic Kidney Disease

Phase II Clinical Study in CKD Caused by IgA Nephropathy and in African Americans with Hypertension – Enrollment Continues

The Phase II REDUX (latin for restore) trial is a multi-center, open-label investigation of approximately 60 participants with chronic kidney disease (CKD), who are being enrolled in two cohorts (30 per cohort). The study is ongoing in the United States at 12 sites and targets participants with CKD: Cohort I is enrolling non-diabetic, hypertensive African Americans with Stage II or III CKD, a group which is at greater risk for CKD than Caucasians. African Americans who have the APOL1 gene mutation are at an even higher risk. The study is designed to capture the APOL1 gene mutation as an exploratory biomarker in this cohort. Cohort II is enrolling participants with IgA Nephropathy (IgAN). The overall study evaluates two dose levels of DM199. Study participants in each cohort will receive DM199 by subcutaneous injection twice weekly for 95 days. The primary study endpoints include safety, tolerability, blood pressure, proteinuria and kidney function, which will be evaluated by changes from baseline in estimated glomerular filtration rate (eGFR) and albuminuria, as measured by the urinary albumin to creatinine ratio (UACR).

Due to actions implemented to combat the novel strain of the coronavirus (COVID-19) pandemic, the Company is experiencing slower than expected enrollment in the REDUX clinical study as activities are reduced or suspended at the clinical study sites as they address staff and patient safety concerns.The Company currently expects a delay in the timing of costs incurred as a result of the COVID-19 pandemic, but not a significant overall increase. The Company will continue to assess the effect of the pandemic on its REDUX trial by monitoring the spread of the COVID-19 virus and the actions implemented to combat the virus.

"Our highest priority right now is to protect the safety of subjects and clinical staff participating in the REDUX trial, and we believe that we have accomplished that" commented Dr. Harry Alcorn, DiaMedica's Chief Medical Officer. "While enrollment has significantly slowed, we believe that the measures taken will allow our study to resume more normal rates of enrollment as COVID-19 related restrictions are eased."

Public Offering of Common Shares

On February 13, 2020, the Company issued and sold an aggregate of 2,125,000 common shares in a public, underwritten offering at a public offering price of $4.00 per share. As a result of the offering, the Company received gross proceeds of $8.5 million and net proceeds of $7.7 million, after deducting the underwriting discount and offering expenses.

Financial Results

Research and development (R&D) expenses were $1.4 million for the three months ended March 31, 2020, compared with $2.6 million for the three months ended March 31, 2019, a decrease of $1.2 million. The decrease was due to costs incurred during the first quarter of 2019 which did not reoccur during the first quarter of 2020, primarily the costs for a production run of the DM199 drug substance and the Phase Ib study in CKD patients. Declining costs for the ReMEDy study in the current year period also contributed to the decrease. These decreases were partially offset by costs incurred for the REDUX study, which began enrollment in December 2019, and increased non-cash share-based compensation costs.

General and administrative (G&A) expenses were $1.0 million for the three months ended March 31, 2020, up from $814,000 for the three months ended March 31, 2019. The increase in G&A expenses resulted primarily from increased non-cash share-based compensation costs.

Total other (income) expense, net, for the three months ended March 31, 2020 was a net expense of $12,000, compared with net income of $178,000 for the three months ended March 31, 2019. The change was primarily caused by the foreign currency transaction losses associated with funds held in non-functional currency (US dollar) accounts, principally Australian dollars. A decrease in R&D incentives, associated with decreased ReMEDy costs and reductions in interest income earned on marketable securities during the three months ended March 31, 2020, also contribute to this change.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of $12.6 million, current liabilities of $0.9 million and working capital of $13.2 million as of March 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 February 2020 public offering of common shares.

Net cash used in operating activities was $3.0 million for the three months ended March 31, 2020, compared to $3.1 million for the three months ended March 31, 2019. The net cash used in each of these periods primarily reflects the net loss for these periods, offset by non-cash charges for stock-based compensation and adjusted for the net effects of changes in operating assets and liabilities.

Conference Call Information

DiaMedica Management will host a conference call to discuss both its first quarter 2020 financial results and the top-line results from its ReMEDy study on Thursday, May 14, 2020, at 7:00 a.m. Central Time:

Date: Thursday, May 14, 2020
Time: 7:00 AM CT / 8:00 AM ET
Web access: https://event.on24.com/wcc/r/2158468/5BAA62D375A1F892573859D379BAF858
Dial In: (833) 502-0492 (domestic)
(778) 560-2558 (international)
Conference ID: 8757888

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 May 21, 2020, by dialing (800) 585-8367 (US Toll Free), (416) 621-4642 (International), replay passcode 8757888.

About DM199

DM199 is a recombinant (synthetic) form of the human serine protease, KLK1. The KLK1 protein 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. is a clinical stage biopharmaceutical company focused on developing novel treatments for chronic kidney diseases and neurological disorders. DiaMedica shares are listed on The Nasdaq Capital Market under the trading symbol "DMAC."

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 safety and efficacy of DM199; the assessment of the data from the ReMEDy study and the future publication and sharing of the full study results, and regulatory path forward, the timing and requirements of its clinical programs, including enrollment and clinical results and ability to achieve clinical milestones. 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 additional clinical trials of DM199 or from subsequent analysis of existing data from the ReMEDy study or existing or new data received from additional ongoing and future studies 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 CKD and AIS 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; its reliance on collaboration with third parties to conduct clinical trials; its ability to continue to obtain funding for its operations, including funding necessary to complete planned clinical trials and obtain regulatory approvals for DM199 for CKD and AIS, 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, 2019, and subsequent SEC filings by DiaMedica. 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)
(Unaudited)

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 1,381	$ 2,607
General and administrative	1,023	814
Operating loss	(2,404)	(3,421)
Other (income) expense:		
Governmental assistance - research incentives	(115)	(174)
Other (income) expense, net	127	(4)
Total other (income) expense	12	(178)
Loss before income tax expense	(2,416)	(3,243)
Income tax expense	9	9
Net loss	(2,425)	(3,252)
Other comprehensive income		
Unrealized gain on marketable securities	40	3
Net loss and comprehensive loss	$ (2,385)	$ (3,249)
Basic and diluted net loss per share	$ (0.19)	$ (0.27)
Weighted average shares outstanding – basic and diluted	13,107,725	11,956,874

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

	March 31, 2020	December 31, 2019
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,300	$ 3,883
Marketable securities	9,348	3,995
Amounts receivable	985	823
Prepaid expenses and other assets	337	47
Deposits	195	88
Total current assets	14,165	8,836
Non-current assets:		
Operating lease right-of-use asset	140	153
Property and equipment, net	60	64
Total non-current assets	200	217
Total assets	$ 14,365	$ 9,053
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 444	$ 182
Accrued liabilities	435	1,076
Finance lease obligation	6	6
Operating lease obligation	50	54
Total current liabilities	935	1,318
Non-current liabilities:		
Finance lease obligation, non-current	11	13
Operating lease obligation, non-current	96	105
Total non-current liabilities	107	118
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 12,006,874 and 11,956,874 shares issued and outstanding, as of September 30, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	72,323	64,232
Accumulated other comprehensive income	42	2
Accumulated deficit	(59,042)	(56,617)
Total shareholders' equity	13,323	7,617
Total liabilities and shareholders' equity	$ 14,365	$ 9,053

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

	Three Months Ended March 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (2,425)	$ (3,252)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	393	130
Amortization of discount on marketable securities	(14)	(26)
Non-cash lease expense	13	12
Depreciation	6	6
Changes in operating assets and liabilities:		
Amounts receivable	(162)	(150)
Prepaid expenses	(290)	72
Deposits	(107)	—
Accounts payable	262	201
Accrued liabilities	(654)	(127)
Net cash used in operating activities	(2,978)	(3,134)
Cash flows from investing activities:		
Purchase of marketable securities	(8,799)	(10,928)
Maturities of marketable securities	3,500	—
Purchase of property and equipment	(2)	—
Net cash used in investing activities	(5,301)	(10,928)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	7,682	—
Proceeds from the exercise of stock options	16	—
Principal payments on finance lease obligations	(2)	(2)
Net cash provided by financing activities	7,696	(2)
Net increase (decrease) in cash and cash equivalents	(583)	(14,064
Cash and cash equivalents at beginning of period	3,883	16,823
Cash and cash equivalents at end of period	$ 3,300	$ 2,759

View source version on businesswire.com:
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