May 4, 2022

DiaMedica Therapeutics Provides a Business Update and Announces First Quarter 2022 Financial Results

Conference Call and Webcast May 5 at 8:00 am Eastern Time / 7:00 am Central Time

- ***Continuing to Expand Clinical Study Sites in Pivotal Phase 2/3 ReMEDy2 Acute Ischemic Stroke Trial***
- ***Cash Runway Into 2024***

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 released financial results for the quarter ended March 31, 2022. DiaMedica will host a conference call on Thursday, May 5, 2022, at 8:00AM Eastern Time / 7:00AM Central Time, to discuss its business update and first quarter financial results.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

DiaMedica reported that it has increased the number of activated clinical trial sites to 9, more than doubling the number of active sites reported in March 2022 and is currently on track with its site activation goals for its ReMEDy2 trial, which is an adaptive design, randomized, double-blind, placebo-controlled trial studying the use of the Company's product candidate, DM199, to treat acute ischemic stroke (AIS). DiaMedica believes that it has experienced slower than expected site activations and enrollment in the ReMEDy2 trial due primarily to staffing shortages and overall resourcing at study sites due to the COVID-19 pandemic and challenges of the study sites managing logistics and compliance for patients discharged from the hospital to an intermediate care facility. The Company is putting resources and processes in place to address both of these issues and expects continued improvement in site activations and patient enrollment over the course of 2022, subject to new pandemic related challenges which may arise for study sites.

DM199 for the Treatment of Chronic Kidney Disease

As previously reported, patient enrollment is completed in DiaMedica's Phase 2 REDUX trial, which 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).

In total, 79 patients were enrolled and initiated treatment, including 21 African American patients in Cohort 1, 25 patients with IgAN in Cohort 2 and 33 patients with Type 2 diabetes

in Cohort 3. The last patient visit was completed in March 2022 and DiaMedica is working to complete the study close-out and the final data analysis while evaluating next steps for the CKD program.

Balance Sheet and Cash Flow

DiaMedica reported total cash and investments of $41.0 million, consisting of cash and cash equivalents of $3.0 million and marketable securities of $38.0 million, current liabilities of $1.4 million and working capital of $40.7 million as of March 31, 2022, compared to total cash and investments of $45.1 million, $1.5 million in current liabilities and $43.9 million in working capital as of December 31, 2021. The decreases in cash and investments and in working capital were due primarily to cash used to fund operating activities during the quarter ended March 31, 2022.

Net cash used in operating activities for the three months ended March 31, 2022, was $3.9 million compared to $4.3 million for the three months ended March 31, 2021. This decrease relates primarily to reduced effects of changes in operating assets and liabilities on the net cash used in operating activities in the current year period.

Financial Results

Research and development (R&D) expenses were $2.0 million for the three months ended March 31, 2022, compared with $2.4 million for the three months ended March 31, 2021, a decrease of $0.4 million. This decrease was driven mainly by a reduction in costs related to the REDUX CKD trial and a lower level of DM199 manufacturing process development work in the current year quarter as compared to the prior year quarter. These decreases were partially offset by increased costs incurred in the ReMEDy2 AIS trial and higher personnel costs related to the expansion of the clinical team in the current year period.

General and administrative (G&A) expenses were $1.6 million for the three months ended March 31, 2022, up from $1.2 million for the three months ended March 31, 2021. This $0.4 million increase resulted from a combination of increased professional services costs, directors' and officers' liability insurance and personnel costs incurred in support of expanding the operations and clinical programs.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and first quarter 2022 financial results on Thursday, May 5, 2022, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Thursday, May 5, 2022
Time:	8:00 AM ET / 7:00 AM CT
Web access:	https://events.q4inc.com/attendee/640421392
Dial In:	(888) 440-4368
Conference ID:	4814247

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 relations - events and presentations, following the earnings call and for 12 months

thereafter. A telephonic replay of the conference call will be available until May 12, 2022, by dialing (800) 770-2030 (US Toll Free) and entering the replay passcode: 4814247.

About ReMEDy2 Trial

The ReMEDy2 trial is an adaptive design, randomized, double-blind, placebo-controlled trial studying the use of the Company's product candidate, DM199, to treat AIS patients. The trial is intended to enroll approximately 350 patients at 75 sites in the United States. Patients enrolled in the trial will be treated for three weeks with either DM199 or placebo, beginning within 24 hours of the onset of AIS symptoms, with the final follow-up at 90 days. The trial excludes patients treated with tissue plasminogen activator (tPA) and/or mechanical thrombectomy. The study population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA or mechanical thrombectomy. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

The ReMEDy2 trial has two separate, independent, primary endpoints based upon both the results observed in the first ReMEDy1 phase 2 trial and published results from the urine-derived form of KLK1 used to successfully treat AIS in China. ReMEDy2 is powered for success with either endpoint: 1) physical recovery from stroke as measured by the well-established modified Rankin Scale (mRS) at day 90, and 2) the rate of ischemic stroke recurrence through day 90. Recurrent strokes represent 25% of all ischemic strokes, often occurring in the first few weeks after an initial stroke and are typically more disabling, costly, and fatal than initial strokes.

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 stroke, chronic kidney disease, retinopathy, 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 South Korea for decades. DM199 is currently being studied in patients with acute ischemic stroke and patients with chronic kidney disease. In September 2021, the U.S. Food and Drug Administration granted Fast Track Designation to DM199 for the treatment of acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering serious diseases. Its lead candidate, DM199, is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality for the treatment of acute ischemic stroke and chronic kidney disease. For more information visit the Company's website at 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," "potential," "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 Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes has the potential to serve as a pivotal registration study of DM199 in that patient population, the potential for each of the two separate independent primary endpoints to be the basis for regulatory approval of DM199 for the treatment of AIS; anticipated site activations, including its expectation for continued improvement in site activations and patient enrollment over the course of 2022, anticipated clinical results and ability to achieve clinical and other milestones and its goal of offering a treatment option for patients who suffer from AIS. 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 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, enrollment numbers, costs and timeframes; the adaptive design of the ReMEDy2 trial and the possibility that the targeted enrollment and other aspects of the trial could change depending upon certain factors, including additional input from the FDA and the blinded interim analysis; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic, hospital and medical facility staffing shortages, and worldwide global supply chain shortages on DiaMedica's business and clinical trials, including its ability to meet its site activation and enrollment goals; 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, 2021 and subsequent U.S. Securities and Exchange Commission filings. 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.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 1,974	$ 2,406
General and administrative	1,562	1,213
Operating loss	(3,536)	(3,619)
Other income:		
Other income, net	35	4
Total other income, net	35	4
Loss before income tax expense	(3,501)	(3,615)
Income tax expense	(7)	(7)
Net loss	(3,508)	(3,622)
Other comprehensive loss		
Unrealized loss on marketable securities	(56)	(2)
Net loss and comprehensive loss	$ (3,564)	$ (3,624)
Basic and diluted net loss per share	$ (0.13)	$ (0.19)
Weighted average shares outstanding – basic and diluted	26,443,067	18,766,656

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

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,032	$ 4,707
Marketable securities	38,015	40,405
Amounts receivable	168	130
Deposits	103	113
Prepaid expenses and other assets	793	84
Total current assets	42,111	45,439
Non-current assets:		
Property and equipment, net	74	70
Operating lease right-of-use asset	26	42
Total non-current assets	100	112
Total assets	$ 42,211	$ 45,551
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 433	$ 509
Accrued liabilities	967	966
Finance lease obligation	6	4
Operating lease obligation	28	45
Total current liabilities	1,434	1,524
Non-current liabilities:		
Finance lease obligation, non-current	9	3
Total non-current liabilities	9	53
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding as of March 31, 2022 and December 31, 2021	—	—
Paid-in capital	126,884	126,576
Accumulated other comprehensive loss	(107)	(51)
Accumulated deficit	(86,009)	(82,501)
Total shareholders' equity	40,768	44,024
Total liabilities and shareholders' equity	$ 42,211	$ 45,551

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (3,508)	$ (3,622)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	308	511
Amortization of discount on marketable securities	120	26
Non-cash lease expense	15	14
Depreciation	6	6
Changes in operating assets and liabilities:		
Amounts receivable	(38)	3
Deposits	10	—
Prepaid expenses and other assets	(709)	(383)
Accounts payable	(76)	(410)
Accrued liabilities	(16)	(458)
Net cash used in operating activities	(3,888)	(4,313)
Cash flows from investing activities:		
Purchase of marketable securities	(13,379)	(11,923)
Maturities of marketable securities	15,593	11,921
Purchases of property and equipment	—	(9)
Proceeds from disposition of property and equipment	—	2
Net cash provided by (used in) investing activities	2,214	(9)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	—	244
Principal payments on finance lease obligations	(1)	(2)
Net cash provided by (used in) financing activities	(1)	242
Net decrease in cash and cash equivalents	(1,675)	(4,080)
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	$ 3,032	$ 3,329
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	$ 10	$ —

View source version on businesswire.com:
https://www.businesswire.com/news/home/20220504005795/en/

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