May 15, 2023

DiaMedica Therapeutics Provides a Business Update and Announces First Quarter 2023 Financial Results

Conference Call and Webcast May 16 at 8:00 am Eastern Time / 7:00 am Central Time

- ***Company Completed In-Use Study, Results Support Proposed ReMEDy2 IV Dose Revision***
- ***Company Completed a Phase 1C Study in Healthy Volunteers in Australia Affirming Proposed Revised DM199 IV Dose of 0.5 µg/kg for Continuing the ReMEDy2 Trial***
- ***DiaMedica Plans to File Complete Clinical Hold Response This Week***
- ***Cash Runway Into Q4 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 financial results for the quarter ended March 31, 2023. Management will host a conference call Tuesday, May 16, 2023, at 7:00AM Central Daylight Time/8:00AM Eastern Daylight Time to discuss its business update and first quarter 2023 financial results.

Clinical Developments

ReMEDy2 Phase 2/3 Trial for Acute Ischemic Stroke – Clinical Hold Update

DiaMedica plans to file complete response requesting hold lift this week

DiaMedica plans to file a clinical hold response with the U.S. Food and Drug Administration (FDA) by the end of the week. This request for lifting the clinical hold will include the submission of requested additional supporting data to address prior issues that led to the clinical hold in July 2022. DiaMedica has completed supplemental in-use studies as requested by the FDA. These studies, performed at an independent laboratory, were conducted in two parts. Part 1 simulated actual use of DM199 administration in a hospital setting and Part 2 evaluated worst-case scenarios such as varying storage durations, temperature(s) and light exposure to DM199. DiaMedica believes data from Part 1 confirmed its conclusions from prior testing that the intravenous (IV) dose administered in the ReMEDy2 study was higher than planned due to the change in IV bag materials and was the cause of the hypotension. Accordingly, a dose revision in ReMEDy2 from 1.0 µg/kg to 0.5 µg/kg should avoid or minimize the risk of clinically significant hypotension while still reaching what we believe will be a therapeutic blood concentration level. Additionally, results from part 2 of the in-use study were substantially consistent with Part 1 indicating that no special handling instructions should be required. These results are also similar to the Company's IV bag study completed in the fall of 2022. The Company further notes that there

are no proposed changes to the ensuing three weeks of subcutaneous dosing under the study protocol.

As previously announced, the Company provided responses to FDA inquiries on a potential trypsin impurity contributing to hypotension and methods assays to be used to measure results in the in-use study. The FDA responded to the Company indicating that the assays developed for the in-use study appeared appropriate and its assessment of the potential trypsin impurity was also acceptable.

“With the pending submission of our request to lift the clinical hold, we are optimistic that we have fully identified the cause for last year’s unexpected hypotensive events and have provided the FDA with adequate data to support our position and allow the FDA to lift the clinical hold,” commented Rick Pauls, DiaMedica’s Chief Executive Officer. “We look forward to receiving the FDA’s response and hope to then be able to resume our work advancing the science of stroke care.”

DiaMedica also completed, in healthy volunteers, a Phase 1C open label, single ascending dose (SAD) study of DM199, administered with the polyvinylchloride (PVC) IV bags used in the ReMEDy2 trial. The purpose of the study was to confirm, with human data, that the revised IV dose of DM199, 0.5 µg/kg, was well-tolerated in humans and achieved an appropriate DM199 blood concentration level similar to prior clinical trials and in the desired therapeutic range. The results from this study will be included as additional supporting data in the Company’s clinical hold response package to the FDA.

“Patient safety is paramount for DiaMedica and we’re pleased to go above and beyond to achieve that end,” stated Kirsten Gruis, M.D., DiaMedica’s Chief Medical Officer. “Data developed in our Phase 1C study at the 0.5 µg/kg IV dose level has demonstrated similar DM199 exposure with the IV dosing regimen used in our ReMEDy1 AIS trial. These results, in addition to the in-use study, give us further assurance that we have identified the correct DM199 IV dose level and we hope that this will also give confidence to physician investigators once we are able to resume the ReMEDy2 trial.”

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $28.7 million, current liabilities of $2.8 million and working capital of $26.9 million as of March 31, 2023, compared to total cash, cash equivalents and investments of $33.5 million, $2.2 million in current liabilities and $31.7 million in working capital as of December 31, 2022. 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, 2023. After the end of the quarter, DiaMedica received $750,000 from a private investment from its newly appointed Chief Business Officer.

Net cash used in operating activities for the three months ended March 31, 2023 was $5.1 million compared to $3.9 million for the three months ended March 31, 2022. The increase in cash usage relates primarily to the increased net loss in the current year period over the prior year period, partially offset by non-cash share-based compensation and the effects of changes in operating assets and liabilities in the current year period.

Financial Results

Research and development (R&D) expenses increased to $3.6 million for the three months ended March 31, 2023, up $1.6 million from $2.0 million for the three months ended March 31, 2022. The increased costs were driven by a number of factors, including primarily increased manufacturing and process development costs, the costs for the in-use study performed to address the clinical hold on the IND for the ReMEDy2 trial, costs incurred for the Phase 1C health volunteer study and increased personnel costs associated with expansion of the clinical team. These increases were partially offset by decreased costs incurred in the Phase 2/3 ReMEDy2 trial due to the clinical hold.

General and administrative (G&A) expenses were $1.9 million for the three months ended March 31, 2023, up from $1.6 million for the three months ended March 31, 2022. The increase was primarily due to recruiting costs incurred in conjunction the expansion of the Company's team and increased legal fees incurred in connection with the Company's lawsuit against Pharmaceutical Research Associates Group B.V., which was acquired by and is now a subsidiary of ICON plc.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and first quarter 2023 financial results on Tuesday, May 16, 2023, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Tuesday, May 16, 2023
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://app.webinar.net/r4298p1YBXV
Dial In:	(877) 550-1858
Conference ID:	2125#

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 the Company'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 23, 2023, by dialing (800) 645-7964 (US Toll Free) and entering the replay passcode: 2125#.

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 acute ischemic stroke (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.

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 and clinically studied a recombinant form of the KLK1 protein. The KLK1 protein, produced from the pancreas of pigs 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 (AIS) and patients with chronic kidney disease. In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of AIS.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases. DiaMedica's lead candidate DM199 is the first pharmaceutically active recombinant (synthetic) form of the KLK1 protein, an established therapeutic modality in Asia 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 "anticipates," "believes," "look forward," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "hope," "should," or "will," 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 Company's expectations regarding the timing of its complete clinical hold response, its ability to resolve the clinical hold imposed by the FDA and the timing thereof, and its belief that the issues raised by the FDA are potentially addressable, the resumption of the ReMEDy2 trial, and the anticipated clinical benefits and success of DM199. 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 risk that the Company may not be able to provide objective evidence acceptable to the FDA substantiating the Company's belief as to the cause of the hypotension events that occurred and led to the clinical hold or that its plan to resolve the issues and prevent future events may not be successful; the risk that the Company may not be able to address sufficiently the concerns identified by the FDA or may require the Company to collect additional data or information beyond what the FDA has currently requested and what the Company currently expects; the Company's ability to successfully

engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding the ReMEDy2 trial and the timing and outcome of the Company's planned interactions with the FDA concerning the related clinical hold; the risk that the Company may not be able to lift the clinical hold or do so in a timely manner; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that FDA may not remove the clinical hold on the ReMEDy2 trial; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; 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 acute ischemic stroke and chronic kidney disease 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 COVID-19, 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 acute ischemic stroke and chronic kidney disease, 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, 2022 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,	
	2023	**2022**
Operating expenses:		
Research and development	$ 3,618	$ 1,974
General and administrative	1,903	1,562
Operating loss	(5,521)	(3,536)
Other income:		
Other income, net	256	35
Total other income, net	256	35
Loss before income tax expense	(5,265)	(3,501)
Income tax expense	(7)	(7)
Net loss	(5,272)	(3,508)
Other comprehensive loss		
Unrealized loss on marketable securities	45	(56)
Net loss and comprehensive loss	$ (5,227)	$ (3,564)
Basic and diluted net loss per share	$ (0.20)	$ (0.13)
Weighted average shares outstanding – basic and diluted	26,448,941	26,443,067

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

	March 31, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,147	$ 4,728
Marketable securities	26,508	28,774
Prepaid expenses and other assets	962	251
Amounts receivable	57	82
Total current assets	29,674	33,835
Non-current assets:		
Operating lease right-of-use asset	407	424
Property and equipment, net	136	136
Total non-current assets	543	560
Total assets	$ 30,217	$ 34,395
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 1,780	$ 734
Accrued liabilities	956	1,365
Operating lease obligation	73	63
Finance lease obligation	5	6
Total current liabilities	2,814	2,168
Non-current liabilities:		
Operating lease obligation, non-current	377	396
Finance lease obligation, non-current	4	4
Total non-current liabilities	381	400
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,464,977 and 26,443,067 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	—	—
Paid-in capital	128,500	128,078
Accumulated other comprehensive loss	(29)	(74)
Accumulated deficit	(101,449)	(96,177)
Total shareholders' equity	27,022	31,827
Total liabilities and shareholders' equity	$ 30,217	$ 34,395

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

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (5,272)	$ (3,508)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	422	308
Amortization of discount on marketable securities	(205)	120
Non-cash lease expense	17	15
Depreciation	7	6
Changes in operating assets and liabilities:		
Amounts receivable	25	(38)
Prepaid expenses and other assets	(711)	(699)
Accounts payable	1,046	(76)
Accrued liabilities	(418)	(16)
Net cash used in operating activities	(5,089)	(3,888)
Cash flows from investing activities:		
Purchase of marketable securities	(9,824)	(13,379)
Maturities of marketable securities	12,340	15,593
Purchases of property and equipment	(7)	—
Net cash provided by investing activities	2,509	2,214
Cash flows from financing activities:		
Principal payments on finance lease obligations	(1)	(1)
Net cash used in financing activities	(1)	(1)
Net decrease in cash and cash equivalents	(2,581)	(1,675)
Cash and cash equivalents at beginning of period	4,728	4,707
Cash and cash equivalents at end of period	$ 2,147	$ 3,032
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	$ —	$ 10
Cash paid for income taxes	$ 14	$ 7

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