March 28, 2023

DiaMedica Therapeutics Provides a Business Update and Announces Full Year 2022 Financial Results

Conference Call and Webcast March 29 at 8:00 am Eastern Time / 7:00 am Central Time

- ***Company has had Ongoing and Successful Communications with the FDA to Address the Clinical Hold***
- ***Company Completed Part 1 of In-Use Study, Results Support Proposed ReMEDy2 Dose Revision***
- ***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 year ended December 31, 2022. Management will host a conference call Wednesday, March 29, 2023, at 7:00AM Central Daylight Time/8:00AM Eastern Daylight Time to discuss its business update and full year 2022 financial results.

Clinical Developments

ReMEDy2 Phase 2/3 Trial - Clinical Hold Update

In July 2022, the U.S. Food and Drug Administration (FDA) placed a clinical hold on the Company's Phase 2/3 ReMEDy2 trial following the Company voluntarily pausing patient enrollment in the trial to investigate three unexpected instances of clinically significant hypotension (low blood pressure) occurring shortly after initiation of intravenous (IV) dose of DM199. The hypotension was transient and blood pressure levels of all three patients recovered back to baseline within minutes of stopping the infusion and the patients suffered no ongoing adverse effects.

In October 2022, the Company announced that the FDA continued the clinical hold and requested that the Company perform an additional in-use in vitro stability study of the IV administration of DM199 to fully identify all potential factors causing or contributing to the three unexpected instances of clinically significant hypotension occurring shortly after initiation of the IV dose of DM199. An in-use study includes testing the combination of the IV bag, IV tubing and any materials used during the infusion that come in contact with DM199 and the mechanical infusion pump in a manner that simulates the actual usage in a hospital. In December 2022, DiaMedica received written comments from the FDA clarifying its expectations for the design of the in-use study. These comments were incorporated into the study protocol and submitted to the FDA. In response, the FDA recently indicated that the protocol appeared to be reasonable. The requested in-use study has been initiated and is

being performed at an independent laboratory. The study is being conducted in two parts. Part 1 simulates actual use in the hospital and part 2 tests worst-case scenarios such as varying storage durations, temperature(s) and light. Part 1 is complete. DiaMedica believes data from part 1 confirms its conclusions from prior testing that the 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, and that a dose revision in ReMEDy2 should avoid the clinically significant hypotension. DiaMedica has submitted these results and conclusions to the FDA for feedback and to confirm that all issues of the clinical hold will have been addressed after submission of data from part 2 of the in-use testing anticipated in April 2023.

The FDA also requested information on a potential trypsin impurity contributing to hypotension and methods assays to be used to measure results in the in-use study. The Company provided responses confirming that trypsin was not a measurable impurity and provided updated validated methods assays to the FDA for review. The Company received FDA feedback that the assays developed for the in-use study appear appropriate and its approaches and assessment to the potential trypsin impurity are also acceptable.

“With the completion of the in-use study at hand, we look forward to continuing to work with the FDA to confirm that we have addressed all issues of the clinical hold and then prepare our complete response requesting a lifting of the clinical hold,” commented Rick Pauls, DiaMedica’s Chief Executive Officer. “We believe that we’ve addressed the issues raised by the FDA and are optimistic that the results of the in-use study will fully and finally confirm the cause of the hypotensive events.”

DiaMedica also announced that it has proactively initiated 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 is to confirm, with human data, the DM199 serum concentration level achieved with the IV dose and further evaluate safety and tolerability. In the event that the FDA does not agree that the results of the in-use study support the proposed dose revision, the data from this Phase 1C study can be used to support the rationale for the IV dose selected for the ReMEDy2 trial. The Phase 1C study is being conducted in Australia and is intended to enroll up to 15 healthy, adult participants. Enrollment in the study has commenced and preliminary data is expected to be available in May 2023.

“Patient safety is paramount for DiaMedica and we’re pleased to go above and beyond to achieve that end,” stated Kirsten Gruis, DiaMedica’s Chief Medical Officer. “Data developed in our Phase 1C study will ensure that we have the correct IV dose level and give confidence to physician investigators once we are able to resume ReMEDy2.”

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $33.5 million, current liabilities of $2.2 million and working capital of $31.7 million as of December 31, 2022, compared to total cash, cash equivalents 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, cash equivalents and investments and in working capital were due to cash used to fund operating activities during the year ended December 31, 2022.

Net cash used in operating activities was $11.5 million and $12.3 million for the years ended

December 31, 2022 and December 31, 2021, respectively. Cash used in operating activities is driven primarily by the Company's net loss, partially offset by a reduction in non-cash share-based compensation and the effects of the changes in operating assets and liabilities.

Financial Results

Research and development (R&D) expenses decreased to $7.8 million for the year ended December 31, 2022, down $1.0 million from $8.8 million for the year ended December 31, 2021. The decrease was driven primarily by reduced costs incurred during 2022 for the wrap-up of the REDUX Phase 2 CKD trial and decreased non-clinical testing costs which were incurred during 2021 in preparation for initiating the Phase 2/3 ReMEDy2 trial. These decreases were partially offset by increased personnel costs associated with expanding the Company's R&D operations and increased manufacturing process development activities.

General and administrative (G&A) expenses were $6.2 million for the year ended December 31, 2022, up from $4.9 million for the year ended December 31, 2021. The increase was primarily driven by increased directors' and officers' liability insurance, increased personnel and professional services costs to support its expanding clinical programs, and increased legal fees for its lawsuit against Pharmaceutical Research Associates Group B.V. These increases were partially offset by a reduction in non-cash, share-based compensation.

Note for U.S. Shareholders

DiaMedica concluded that it should be considered a passive foreign investment corporation (PFIC) for fiscal 2022. Accordingly, DiaMedica has included the required PFIC Information Statement on its website (https://www.diamedica.com/investors/financial-reports/tax-information-pfic) to allow U.S. investors, if desired after consultation with their tax advisors, to make the qualified electing fund (QEF) election on IRS Form 8621 in order to mitigate the potential adverse tax consequences associated with the Company being a PFIC. Each investor will need to review the PFIC tax consequences and available alternative elections with their tax advisor to determine the best course of action in their particular situation.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and full year 2022 financial results on Wednesday, March 29, 2023, at 7:00AM Central Time:

Date:	Wednesday, March 29, 2023
Time:	7:00 AM CDT / 8:00 AM EDT
Web access:	https://app.webinar.net/OZWB76e3RGX
Dial In:	(877) 550-1858
Conference ID:	1754341

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 April 5, 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 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," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "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 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 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 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)

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 7,839	$ 8,765
General and administrative	6,162	4,881
Total operating expenses	14,001	13,646
Operating loss	(14,001)	(13,646)
Other income:		
Other income, net	353	82
Total other income, net	353	82
Loss before income tax expense	(13,648)	(13,564)
Income tax expense	(28)	(28)
Net loss	(13,676)	(13,592)
Other comprehensive loss		
Unrealized loss on marketable securities	(23)	(49)
Net loss and comprehensive loss	$ (13,699)	$ (13,641)
Basic and diluted net loss per share	$ (0.52)	$ (0.65)
Weighted average shares outstanding – basic and diluted	26,443,067	20,773,399

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

	December 31, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,728	$ 4,707
Marketable securities	28,774	40,405
Prepaid expenses and other assets	251	197
Amounts receivable	82	130
Total current assets	33,835	45,439
Non-current assets:		
Operating lease right-of-use asset	424	42
Property and equipment, net	136	70
Total non-current assets	560	112
Total assets	$ 34,395	$ 45,551
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 734	$ 509
Accrued liabilities	1,365	966
Finance lease obligation	6	4
Operating lease obligation	63	45
Total current liabilities	2,168	1,524
Non-current liabilities:		
Finance lease obligation, non-current	4	3
Operating lease obligation, non-current	396	—
Total non-current liabilities	400	3
Commitments and Contingencies		
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding, as of December 31, 2022 and December 31, 2021, respectively	—	—
Paid-in capital	128,078	126,576
Accumulated other comprehensive loss	(74)	(51)
Accumulated deficit	(96,177)	(82,501)
Total shareholders' equity	31,827	44,024
Total liabilities and shareholders' equity	$ 34,395	$ 45,551

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

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (13,676)	$ (13,592)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,502	1,558
Amortization of discount on marketable securities	(11)	161
Non-cash lease expense	64	58
Depreciation	25	24
Changes in operating assets and liabilities:		
Amounts receivable	48	210
Prepaid expenses and other assets	(54)	(123)
Accounts payable	225	(590)
Accrued liabilities	366	42
Net cash used in operating activities	(11,511)	(12,252)
Cash flows from investing activities:		
Purchase of marketable securities	(45,684)	(69,813)
Maturities of marketable securities	57,303	49,296
Purchase of property and equipment	(81)	(22)
Disposition of property and equipment, net	—	2
Net cash provided by (used in) investing activities	11,538	(20,537)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	—	29,849
Proceeds from exercise of stock options	—	244
Principal payments on finance lease obligations	(6)	(6)
Net cash provided by (used in) financing activities	(6)	30,087
Net increase (decrease) in cash and cash equivalents	21	(2,702)
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	$ 4,728	$ 4,707
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ 27	$ 28

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Scott Kellen
Chief Financial Officer
Phone: (763) 496-5118
skellen@diamedica.com

Paul Papi
Corporate Communications
Phone: (617) 899-5941
ppapi@diamedica.com

Source: DiaMedica Therapeutics Inc.