November 9, 2022

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

- ***Company to Conduct In-Use Study to Address FDA Latest Information Request***
- ***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 released financial results for the quarter ended September 30, 2022.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

On October 26, 2022, the Company announced that it received further guidance from the U.S. Food and Drug Administration (FDA) regarding the clinical hold on its ReMEDy2 Phase 2/3 trial. The FDA stated it is maintaining its clinical hold at this time and that additional non-clinical data related to the materials used by a hospital in the intravenous (IV) infusion process is needed to resolve the clinical hold.

In response to the FDA's clinical hold letter in July 2022 related to three serious adverse event cases of transient acute hypotension during intravenous infusion of DM199, the Company previously submitted to the FDA supporting *in vitro* data that the etiology (cause) is likely related to switching the type of IV bag used in the prior ReMEDy 1 trial, where no hypotensive episodes were reported, versus the current ReMEDy 2 trial. Hypotension is a known response to DM199 treatment. Significant differences in protein binding were observed between the two types of IV bags used in the studies that the Company believes effectively altered the total amount of drug being administered. Following review of this data, the FDA requested an additional in-use *in vitro* stability study of the IV administration of DM199 which includes the IV tubing and mechanical infusion pump to further rule out any etiology other than IV bag protein binding.

"Preparation for the *in vitro* study is already underway and we are also preparing to request a Type A FDA meeting in the coming weeks to obtain additional guidance towards lifting the clinical hold and resuming the ReMEDy2 trial," commented Rick Pauls, DiaMedica's Chief Executive Officer. "We will provide an update on the timing of completion of the in-use in-vitro study and data submission following consultation with the FDA."

The 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 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.

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $36.1 million, current liabilities of $1.5 million and working capital of $34.9 million as of September 30, 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 and investments and in working capital were due primarily to cash used to fund operating activities during the nine months ended September 30, 2022.

Net cash used in operating activities was $8.7 million and $9.4 million for the nine months ended September 30, 2022 and September 30, 2021, respectively. Cash used in operating activities is driven primarily by the Company's net loss, partially offset by 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 $1.6 million for the three months ended September 30, 2022, down $0.7 million from $2.3 million for the three months ended September 30, 2021. R&D expenses decreased to $5.6 million for the nine months ended September 30, 2022, down $1.3 million from $6.9 million for the nine months ended September 30, 2021. The decrease for the nine-month comparison was driven primarily by reduced costs incurred during the wrap-up of the REDUX Phase 2 CKD trial and decreased non-clinical testing and manufacturing process development costs which were incurred during 2021 in preparation for initiating the Phase 2/3 ReMEDy2 trial. These decreases were partially offset by increased costs incurred in performing the Phase 2/3 ReMEDy2 trial, inclusive of costs incurred during the clinical hold, and increased personnel costs associated with expanding the Company's R&D operations.

General and administrative (G&A) expenses were $1.5 million for the three months ended September 30, 2022, up from $1.1 million for the three months ended September 30, 2021. G&A expenses were $4.5 million for the nine months ended September 30, 2022, up from $3.5 million for the nine months ended September 30, 2021. The increase for the nine-month comparison was primarily due to increased directors' and officers' liability insurance, and personnel and professional services costs to support our expanding clinical programs. These increases were partially offset by a reduction in non-cash share-based compensation.

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 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 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 "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 Company's expectations regarding its ability to resolve the clinical hold imposed by the FDA 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, including being a potentially life changing drug to stroke patients. 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 know the cause of the hypotension events that occurred in the ReMEDy2 trial 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 successfully 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 clinical hold on the ReMEDy2 trial; 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, 2021 and subsequent U.S. Securities and Exchange Commission filings, including its quarterly report on Form 10-Q for the quarterly period ended September 30, 2022. 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 September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 1,640	$ 2,332	$ 5,569	$ 6,894
General and administrative	1,488	1,084	4,459	3,506
Operating loss	(3,128)	(3,416)	(10,028)	(10,400)
Other income:				
Other income (loss), net	76	(27)	124	75
Loss before income tax expense	(3,052)	(3,443)	(9,904)	(10,325)
Income tax expense	(7)	(7)	(21)	(21)
Net loss	(3,059)	(3,450)	(9,925)	(10,346)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	5	(2)	(111)	(3)
Net loss and comprehensive loss	$ (3,054)	$ (3,452)	$ (10,036)	$ (10,349)
Basic and diluted net loss per share	$ (0.12)	$ (0.18)	$ (0.38)	$ (0.55)
Weighted average shares outstanding – basic and diluted	26,443,067	19,035,713	26,443,067	18,863,829

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

	September 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,771	$ 4,707
Marketable securities	33,313	40,405
Prepaid expenses and other assets	322	84
Amounts receivable	75	130
Deposits	9	113
Total current assets	36,490	45,439
Non-current assets:		
Operating lease right-of-use asset	441	42
Property and equipment, net	110	70
Total non-current assets	551	112
Total assets	$ 37,041	$ 45,551
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 864	$ 509
Accrued liabilities	637	966
Operating lease obligation	34	45
Financing lease obligation	7	4
Total current liabilities	1,542	1,524
Non-current liabilities:		
Operating lease obligation, non-current	415	—
Finance lease obligation, non-current	5	3
Total non-current liabilities	420	3
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Paid-in capital	127,667	126,576
Accumulated other comprehensive loss	(162)	(51)
Accumulated deficit	(92,426)	(82,501)
Total shareholders' equity	35,079	44,024
Total liabilities and shareholders' equity	$ 37,041	$ 45,551

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

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (9,925)	$ (10,346)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,091	1,260
Amortization of premium on marketable securities	118	51
Non-cash lease expense	47	43
Depreciation	19	18
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(238)	(129)
Amounts receivable	55	236
Deposits	104	(133)
Accounts payable	355	(400)
Accrued liabilities	(371)	(48)
Net cash used in operating activities	(8,745)	(9,448)
Cash flows from investing activities:		
Purchase of marketable securities	(35,895)	(47,740)
Maturities of marketable securities	42,758	35,905
Purchases of property and equipment	(49)	(15)
Proceeds from disposition of property and equipment	—	2
Net cash provided by (used in) investing activities	6,814	(11,848)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	—	29,867
Proceeds from the exercise of stock options	—	244
Principal payments on finance lease obligations	(5)	(5)
Net cash (used in) provided by financing activities	(5)	30,106
Net (decrease) increase in cash and cash equivalents	(1,936)	8,810
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	$ 2,771	$ 16,219
Supplemental disclosure of non-cash transactions:		
Assets acquired under operating lease	$ 446	$ —
Assets acquired under financing lease	$ 10	$ —

View source version on businesswire.com:
https://www.businesswire.com/news/home/20221109005758/en/

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

Paul Papi
Corporate Communications
Phone: (508) 444-6790
ppapi@diamedica.com

Source: DiaMedica Therapeutics Inc.