

November 13, 2024



# DiaMedica Therapeutics Provides a Business Update and Announces Third Quarter 2024 Financial Results

***Conference Call and Webcast Thursday November 14 at 8:00 AM Eastern Time / 7:00 AM Central Time***

- **Implemented Updates to AIS Program Intended to Enhance Probability of Trial Success and Expedite Study Completion, with Potential for a Reduced Study Size**
- **Preeclampsia Phase 2 Trial Received Regulatory Approval and First Patient Dosed**
- **Cash Runway Into Q3 2026**

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for severe ischemic diseases, today provided a business update and financial results for the quarter ended September 30, 2024. Management will host a conference call Thursday, November 14, 2024, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and third quarter 2024 financial results.

## **Updates to ReMEDy2 Acute Ischemic Stroke (AIS) Phase 2/3 Protocol and Statistical Analysis Plan**

Following in-depth discussions of the ReMEDy2 trial with current and prospective investigators, stroke experts and its scientific advisory board, the Company has made certain additional updates to the protocol intended to enhance the probability of success for the trial, principally through two modifications: broadening the trial population to include patients not responding to thrombolytic treatment (tissue plasminogen activator (tPA) or tenecteplase (TNK)) and increasing the sample size of the planned interim analysis. These changes were submitted the United States Food and Drug Administration (FDA) on August 30, 2024, and as no FDA comments have been received to-date, the Company is proceeding with implementation..

The first modification of expanding the trial population will capture patients expected to demonstrate a strong treatment response with a low placebo response, potentially enhancing the primary outcome measure for the ReMEDy2 trial. These patients are considered “non-responders” if they receive thrombolytic therapy but retain a persistent neurologic deficit, meaning that their stroke symptoms do not improve, six or more hours following administration of the thrombolytic. In the Company’s prior ReMEDy1 Phase 2 stroke trial, the subgroup of patients who received tPA (n=20) prior to enrollment showed the highest response rate of any group, with these patients receiving DM199 or placebo an average of 13.5 hours post-tPA administration, indicating that the participants did have a persistent

neurological deficit prior to randomization. The Company further notes that including these patients has the potential to significantly accelerate enrollment.

The second modification follows additional statistical modeling of the adaptive design study whereby the interim analysis will be conducted when 200 subjects are treated instead of the previously proposed sample size of 144 subjects. The incremental increase in sample size is intended to increase the precision of the algorithm used to determine the final overall sample size, which we expect will reduce the total number of participants required for the study, thereby reducing the overall trial timeline and trial cost. DiaMedica plans to submit an amended statistical analysis plan (SAP) to the FDA for confirmatory comments.

Together, these protocol and SAP changes are intended to increase the probability of success for the ReMEDy2 trial and expedite overall completion of the study, with potential for a reduced sample size and cost savings.

### **ReMEDy2 Phase 2/3 Clinical Update**

Progress continues with the ReMEDy2 trial site activation activities. The majority of the Company's priority research sites in the United States have been activated. These sites are anticipated to be top enrollment centers for the ReMEDy2 trial and are expected to enroll a disproportionately large share of participants in the trial. DiaMedica recently received approval from Health Canada to conduct the ReMEDy2 trial in Canada and is on track to commence site activations in Canada by the end of the year.

With the adoption of an increased sample size for the interim analysis, the Company now anticipates top line interim results in Q4 2025 compared to the Company's previous guidance of Summer 2025. Patient recruitment will continue while the first 200 participants complete their participation in the trial and the interim analysis is conducted.

"The inclusion of thrombolytic non-responders significantly expands the pool of eligible patients with potential for observing increased treatment responses," stated Dr. Lorianne Masuoka, DiaMedica's Chief Medical Officer. "As we near the completion of activating our high-volume centers, this is expected to catalyze further enrollment momentum."

### **Preeclampsia Phase 2 Investigator-Sponsored Trial**

DM199 is being developed as a disease-modifying treatment to safely extend gestation and improve fetal and maternal outcomes in preeclampsia (PE). DM199's mechanism of action has the potential to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta. On October 9, 2024, DiaMedica announced the receipt of regulatory approval from the South African Health Products Regulatory Authority (SAHPRA) to initiate an investigator-sponsored trial (IST) of DM199 in PE. As reported earlier today, the first patient has been enrolled in the Part 1A dose escalation portion of the Phase 2 study. Top line results from Part 1A are anticipated in the first half of 2025.

The Phase 2 IST is an open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept study of DM199 for the treatment of PE conducted at the Tygerberg Hospital, Cape Town, South Africa. Up to 90 women with PE, and potentially an additional 30 subjects with fetal growth restriction, may be evaluated. Part 1 of the PE study is recruiting women planned for delivery within 72 hours and Part 2 will recruit women in the

expectant management setting. Key outcomes from Part 1 are safety, tolerability, identifying whether DM199 crosses the placental barrier and two efficacy signals of interest to DiaMedica: (1) change in maternal systolic blood pressure (SBP) after infusion and (2) improved baseline uterine artery blood flow.

A replay of the Company's July 29, 2024 Preeclampsia Key Opinion Leader (KOL) Event continues to be available on the DiaMedica website [click here](#).

In conjunction with the webinar, DiaMedica released a white paper titled "The Potential of DM199 to Treat Preeclampsia". The white paper can be downloaded from the Literature & Publications section of DiaMedica.com or [click here](#).

## **Balance Sheet and Cash Flow**

DiaMedica reported total cash, cash equivalents and investments of \$50.2 million, current liabilities of \$4.3 million and working capital of \$46.5 million as of September 30, 2024, compared to total cash, cash equivalents and investments of \$52.9 million, current liabilities of \$2.8 million and working capital of \$50.9 million as of December 31, 2023. The decreases in combined cash, cash equivalents and marketable securities and in working capital are due to the net cash used in operating activities partially offset by the net proceeds received from DiaMedica's June 2024 private placement.

Net cash used in operating activities for the nine months ended September 30, 2024 was \$15.6 million compared to \$14.9 million for the nine months ended September 30, 2023. The increase in cash used in operating activities resulted primarily from the combination of increased net loss and the advance of deposit funds to vendors supporting the ReMEDy2 clinical trial during the current year period, partially offset by changes in operating assets and liabilities during the current year period.

## **Financial Results**

Research and development (R&D) expenses increased to \$5.0 million for the three months ended September 30, 2024, up from \$3.3 million for the three months ended September 30, 2023. R&D expenses increased to \$12.6 million for the nine months ended September 30, 2024, up from \$9.4 million for the nine months ended September 30, 2023. These increases are due primarily to increased costs resulting from the continuation of the ReMEDy2 clinical trial, the expansion of the Company's clinical team and increased manufacturing development activity. These increases were partially offset by decreased costs related to clinical trial work completed in 2023, including the Phase 1C and REDUX trials, and the completion in 2023 of in-use study work performed to address the prior clinical hold on the ReMEDy2 trial. DiaMedica expects R&D expenses to increase moderately relative to recent prior periods as it globally expands the ReMEDy2 trial site activations and participant enrollments continue.

General and administrative (G&A) expenses were \$1.9 million for each of the three month periods ended September 30, 2024 and 2023. G&A expenses were \$5.7 million for the nine months ended September 30, 2024, down from \$6.0 million for the nine months ended September 30, 2023. The decrease for the nine-month comparison resulted from the combination of reductions in the cost of directors and officers liability insurance premiums and decreased legal fees incurred in connection with DiaMedica's lawsuit against PRA

Netherlands and was partially offset by increased personnel costs incurred in conjunction with expanding the team and increased non-cash share-based compensation costs. DiaMedica expects G&A expenses to remain steady as compared to recent prior periods.

Other income, net, was \$616 thousand and \$1.8 million for the three and nine months ended September 30, 2024, respectively, compared to \$693 thousand and \$1.2 million for the three and nine months ended September 30, 2023, respectively. The nine-month comparison increase was driven by increased interest income recognized during the current year period related to a higher average marketable securities balance compared to the prior year period.

## **Conference Call and Webcast Information**

DiaMedica Management will host a conference call and webcast to discuss its business update and third quarter 2024 financial results on Thursday, November 14, 2024 at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date: Thursday, November 14, 2024  
Time: 8:00 AM ET / 7:00 AM CT  
Web access: <https://app.webinar.net/8B2w698gkyb>  
Dial In: (646) 357-8785  
Conference ID: 28056

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 playback 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 November 18, 2024, by dialing (888) 660-6345 (US Toll Free) and entering the replay passcode: 28056#.

## **About the Acute Ischemic Stroke Phase 2/3 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 patients. The trial is intended to enroll approximately 350 patients at up to 100 sites globally. 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 who received mechanical thrombectomy (MT) or participants with large vessel occlusions in the intracranial carotid artery or the M1 segment for the middle cerebral, vertebral or basilar arteries or those that are otherwise eligible for MT. Participants treated with tissue plasminogen activator (tPA) or tenecteplase (TNK), (thrombolytic agents) intended to dissolve blood clots, are eligible for participation if they continue to experience a persistent neurological deficit after receiving thrombolytic treatment and meet all other trial criteria. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

## **About the Preeclampsia Phase 2 Trial**

PE is a serious pregnancy disorder that typically develops after the 20th week of gestation, characterized by high blood pressure and damage to organ systems, often the kidneys and liver. Affecting up to 8% of pregnancies worldwide, preeclampsia can pose significant risks to both the mother and baby, including risk of stroke, placental abruption, progression to

eclampsia, premature delivery, and death. This Phase 2 open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored study of DM199 in treating preeclampsia is being conducted at the Tygerberg Hospital, Cape Town, South Africa (SA), under the direction of Catherine Cluver, MD, PhD, Professor of Maternal/Fetal Medicine, Stellenbosch University, Stellenbosch, SA, in collaboration with DiaMedica. This trial will enroll up to 90 women with preeclampsia and potentially 30 subjects with fetal growth restriction. Dosing commenced in the fourth quarter of 2024. Part 1A top line study results are anticipated in the first half of 2025 and are intended to demonstrate whether DM199 is safe and lowers maternal blood pressure. Additionally, patients with early onset PE will be evaluated for improvements in uterine artery dilation, a sign that DM199 is a potentially disease modifying therapy.

### **About DM199**

DM199 (rinvecalinase alfa) is a recombinant form of human tissue kallikrein-1 (rhKLK1) in clinical development for acute ischemic stroke and preeclampsia. KLK1 is a serine protease enzyme that plays an important role in the regulation of diverse physiological processes via a molecular mechanism that increases production of nitric oxide, prostacyclin and endothelium-derived hyperpolarizing factors. In the case of AIS, DM199 is intended to enhance blood flow and boost neuronal survival in the ischemic penumbra by dilating arterioles surrounding the site of the vascular occlusion and inhibition of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis. In preeclampsia, DM199 is intended to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta.

### **About DiaMedica Therapeutics Inc.**

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious ischemic diseases with a focus on acute ischemic stroke and preeclampsia. 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, preeclampsia and other vascular diseases. For more information visit the Company's website at [www.diamedica.com](http://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," "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 effect of the ReMEDy2 protocol and statistical analysis plan changes and whether they will increase the probability of success for the trial, expedite overall study completion, reduce the sample size and save costs; the timing for additional ReMEDy2 trial site activations and interim enrollment; timing for top line results from Part 1A of the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical

benefits and success of DM199; future operating expenses and cash runway into third quarter of 2026. 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, risks and uncertainties relating to the timing of ReMEDy2 trial site activations and enrollment, regulatory applications and related filing and approval timelines; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; risks and uncertainties relating to the clinical expansion into preeclampsia and the DM199 Phase 2 trial for preeclampsia, including timing of results; 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 preeclampsia and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, site activations, 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 current and planned clinical trials and obtain regulatory approvals for DM199 for acute ischemic stroke and preeclampsia, 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, 2023 and subsequent reports filed with the U.S. Securities and Exchange Commission, including its most recent quarterly report on Form 10-Q for the quarterly period ended September 30, 2024. 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,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 4,983	\$ 3,272	\$ 12,587	\$ 9,433
General and administrative	1,900	1,885	5,675	5,986
Operating loss	(6,883)	(5,157)	(18,262)	(15,419)
Other income:				
Other income, net	616	693	1,739	1,220
Loss before income tax expense	(6,267)	(4,464)	(16,523)	(14,199)
Income tax expense	(7)	(7)	(21)	(21)
Net loss	(6,274)	(4,471)	(16,544)	(14,220)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	132	(64)	75	(53)
Net loss and comprehensive loss	<u>\$ (6,142)</u>	<u>\$ (4,535)</u>	<u>\$ (16,469)</u>	<u>\$ (14,273)</u>
Basic and diluted net loss per share	<u>\$ (0.15)</u>	<u>\$ (0.12)</u>	<u>\$ (0.42)</u>	<u>\$ (0.46)</u>
Weighted average shares outstanding – basic and diluted	<u>42,751,577</u>	<u>37,949,422</u>	<u>39,604,179</u>	<u>30,751,329</u>

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

	September 30, 2024	December 31, 2023
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,134	\$ 4,543
Marketable securities	46,063	48,352
Amounts receivable	290	411
Prepaid expenses and other assets	280	369
Total current assets	50,767	53,675
Non-current assets:		
Deposits	1,308	—
Operating lease right-of-use asset, net	298	354
Property and equipment, net	151	131
Total non-current assets	1,757	485
Total assets	\$ 52,524	\$ 54,160
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 1,171	\$ 926
Accrued liabilities	3,024	1,777
Operating lease obligation	88	80
Finance lease obligation	14	3
Total current liabilities	4,297	2,786
Non-current liabilities:		
Operating lease obligation	249	316
Finance lease obligation	14	1
Total non-current liabilities	263	317
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 42,766,497 and 37,958,000 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Paid-in capital	179,985	166,609
Accumulated other comprehensive income	81	6
Accumulated deficit	(132,102)	(115,558)
Total shareholders' equity	47,964	51,057
Total liabilities and shareholders' equity	\$ 56,791	\$ 54,160



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

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (16,544)	\$ (14,220)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,496	1,227
Amortization of discount on marketable securities	(1,013)	(856)
Non-cash lease expense	56	52
Depreciation	28	22
Changes in operating assets and liabilities:		
Amounts receivable	79	(228)
Prepaid expenses and other assets	131	(860)
Deposits	(1,308)	—
Accounts payable	245	129
Accrued liabilities	1,188	(182)
Net cash used in operating activities	(15,642)	(14,916)
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(39,623)	(64,537)
Maturities of marketable securities	43,000	40,135
Purchases of property and equipment	(18)	(21)
Net cash provided by (used in) investing activities	3,359	(24,423)
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common shares, net of offering costs	11,747	36,848
Proceed from the exercise of common stock options	133	—
Principal payments on finance lease obligation	(6)	(5)
Net cash provided by financing activities	11,874	36,843
Net decrease in cash and cash equivalents	(409)	(2,496)
Cash and cash equivalents at beginning of period	4,543	4,728
Cash and cash equivalents at end of period	<u>\$ 4,134</u>	<u>\$ 2,232</u>
<b>Supplemental disclosure of non-cash transactions:</b>		
Assets acquired under financing lease	\$ 30	\$ —
Cash paid for income taxes	<u>\$ 20</u>	<u>\$ 26</u>

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<https://www.businesswire.com/news/home/20241113470436/en/>

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