

May 8, 2024



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

***Conference Call and Webcast May 9 at 8:00 AM Eastern Time / 7:00 AM Central Time***

- **First Patient Dosed in Relaunch of ReMEDy2 Stroke Trial**
- **Clinical Operations Team Expanded to Support Global Expansion**
- **\$46.5 Million Cash with Runway to 2026**

MINNEAPOLIS--(BUSINESS WIRE)-- DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and cardio-renal disease, today provided a business update and financial results for the quarter ended March 31, 2024. Management will host a conference call Thursday, May 9, 2024 at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and first quarter 2024 financial results.

## **ReMEDy2 Phase 2/3 AIS Clinical Developments**

DiaMedica, as recently announced, enrolled its first participant in the continuation of its ReMEDy2 trial of DM199 (rinvecalinase alfa) in participants with acute ischemic stroke (AIS). The first clinical sites were opened in December 2023 and as of the date of this press release, eight sites have now been opened. The majority of the U.S. sites are expected to be activated by the end of the third quarter of 2024.

Progress is also being made outside of the United States. With the support of the Canadian Stroke Consortium, the required Senior Medical Officer, who will serve as the national physician investigator for Canada, has been engaged and six quality sites have been identified for inclusion in the trial. DiaMedica currently expects to submit its regulatory filings to Health Canada this month and expects a response by the end of June. The activation of study sites in Canada is expected to begin in the fourth quarter of 2024. The Australian Stroke Trials Network has completed its endorsement of DiaMedica's protocol and DiaMedica is currently selecting study sites. The Company plans to work with many of the same highly-engaged centers it worked with in the ReMEDy1 trial. Australian site activation remains on track to commence before the end of 2024.

The Company currently believes that, barring any unforeseen circumstances, full enrollment for the 144 patients for the interim analysis will be completed in the first quarter of 2025. For more information about the ReMEDy2 AIS Phase 2/3 clinical trial, please visit ([www.remedytrial.com](http://www.remedytrial.com)).

"We are diligently working to involve and mobilize top-tier stroke centers, laying a solid groundwork for patient participation," stated Dr. Lorianne Masuoka, DiaMedica's Chief



Medical Officer. "The enthusiasm from premier research sites is uplifting, and we remain dedicated to bringing DM199 to stroke patients."

## **Balance Sheet and Cash Flow**

DiaMedica reported total cash, cash equivalents and investments of \$46.5 million, current liabilities of \$2.6 million and working capital of \$44.9 million as of March 31, 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 cash, cash equivalents and investments and in working capital were due to a combination of net cash used to fund operations, including the advance of deposit funds to vendors supporting the ReMEDy2 trial in the three months ended March 31, 2024.

Net cash used in operating activities for the three months ended March 31, 2024 was \$6.7 million compared to \$5.1 million for the year three months ended March 31, 2023. The increase in cash used in operating activities was driven primarily by the advance of deposit funds to vendors supporting the ReMEDy2 trial in the current year period.

## **Financial Results**

Research and development (R&D) expenses increased to \$3.7 million for the three months ended March 31, 2024, compared to \$3.6 million for the three months ended March 31, 2023. This increase was due to increased costs related to the continuation of the ReMEDy2 trial, and was partially offset by cost reductions related to clinical trial work completed in 2023, namely the Company's Phase 1C and REDUX trials, and the completion in 2023 of in-use study work performed to address the former clinical hold on the ReMEDy2 trial. DiaMedica expects R&D expenses to increase moderately relative to recent prior periods as the global expansion of the ReMEDy2 trial proceeds and site activations and participant enrollments continue. The Company expects these anticipated increases will be moderated by the clinical trial work and in-use studies completed in 2023.

General and administrative (G&A) expenses increased \$0.2 million to \$2.1 million for the three months ended March 31, 2024, up from \$1.9 million for the three months ended March 31, 2023. This increase was primarily driven by increased personnel costs incurred in conjunction with the expansion of DiaMedica's team, partially offset by a reduction in the cost of directors and officers liability insurance premiums. DiaMedica expects G&A expenses to remain steady as compared to prior periods.

Other income, net, was \$597 thousand for the three months ended March 31, 2024 compared to \$256 thousand for the three months ended March 31, 2023. This increase was driven by increased interest income recognized during the three months ended March 31, 2024 related to increased marketable securities balances during the current year period as compared to the same prior year period.

## **Conference Call and Webcast Information**

DiaMedica Management will host a conference call and webcast to discuss its business update and first quarter 2024 financial results on Thursday, May 9, 2024, at 8:00 AM Eastern Time / 7:00 AM Central Time:



Date: Thursday, May 9, 2023  
Time: 8:00 AM ET / 7:00 AM CT  
Web access: <https://app.webinar.net/jDdlNvm9Ewg>  
Dial In: (646) 357-8785  
Conference ID: 07657

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 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 16, 2024, by dialing (888) 660-6345 (US Toll Free) and entering the replay passcode: 07657#.

## **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 patients. The trial is intended to enroll approximately 350 patients at up to 100 sites in the United States with planned global expansion. 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. 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 (rKLK1; rinvecalinase alpha). rKLK1 is identical to naturally produced KLK1, 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 and prostacyclin. In the case of ischemic stroke, the administration of 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 inhibit of apoptosis (neuronal cell death) while also facilitating neuronal remodeling through the promotion of angiogenesis. 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 rKLK1. Non-recombinant, tissue extracted KLK1 protein, produced from the pancreas of pigs and human urine, has been approved for decades outside the U.S. and Europe for patients in Japan, China and South Korea with a variety of ischemic conditions such as AIS, chronic renal disease, retinopathy and hypertension. DM199 is currently being studied in patients with AIS. 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 with a focus on acute ischemic stroke. 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 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," "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 for site activations and geographic locations thereof and enrollment in the ReMEDy2 trial, anticipated clinical benefits and success of DM199, and cash runway to 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, uncertainties relating to the effects of the protocol amendments, timing of 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; 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 cardio-renal 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 cardio-renal 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, 2023 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)

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses:		
Research and development	\$ 3,676	\$ 3,618
General and administrative	2,065	1,903
Total operating expenses	(5,741)	(5,521)
Operating loss	(5,741)	(5,521)
Other income, net	597	256
Loss before income tax expense	(5,144)	(5,265)
Income tax expense	(7)	(7)
Net loss	(5,151)	(5,272)
Other comprehensive income (loss)		
Unrealized gain (loss) on marketable securities	(45)	45
Net loss and comprehensive loss	\$ (5,196)	\$ (5,227)
Basic and diluted net loss per share	\$ (0.14)	\$ (0.20)
Weighted average shares outstanding – basic and diluted	37,958,000	26,448,941



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

	<b>March 31, 2024</b>	<b>December 31,</b>
	(unaudited)	<b>2023</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,097	\$ 4,543
Marketable securities	44,419	48,352
Prepaid expenses and other assets	569	411
Amounts receivable	399	369
Total current assets	47,484	53,675
Non-current assets:		
Deposits	1,308	—
Operating lease right-of-use asset, net	336	354
Property and equipment, net	132	131
Total non-current assets	1,776	485
Total assets	\$ 49,260	\$ 54,160
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 716	\$ 926
Accrued liabilities	1,815	1,777
Operating lease obligation	83	80
Financing lease obligation	3	3
Total current liabilities	2,617	2,786
Non-current liabilities:		
Operating lease obligation, non-current	294	316
Finance lease obligation, non-current	—	1
Total non-current liabilities	294	317
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 37,963,916 and 37,958,000 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	—	—
Paid-in capital	167,097	166,609
Accumulated other comprehensive income (loss)	(39)	6
Accumulated deficit	(120,709)	(115,558)
Total shareholders' equity	46,349	51,057
Total liabilities and shareholders' equity	\$ 49,260	\$ 54,160



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

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (5,151)	\$ (5,272)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	488	422
Amortization of discount on marketable securities	(329)	(205)
Non-cash lease expense	18	17
Depreciation	8	7
Changes in operating assets and liabilities:		
Amounts receivable	(30)	25
Prepaid expenses and other assets	(158)	(711)
Deposits	(1,308)	—
Accounts payable	(210)	1,046
Accrued liabilities	19	(418)
Net cash used in operating activities	(6,653)	(5,089)
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(9,783)	(9,824)
Maturities of marketable securities	14,000	12,340
Purchases of property and equipment	(9)	(7)
Net cash provided by investing activities	4,208	2,509
<b>Cash flows from financing activities:</b>		
Principal payments on finance lease obligations	(1)	(1)
Net cash used in financing activities	(1)	(1)
Net decrease in cash and cash equivalents	(2,446)	(2,581)
Cash and cash equivalents at beginning of period	4,543	4,728
Cash and cash equivalents at end of period	\$ 2,097	\$ 2,147
<b>Supplemental disclosure of non-cash transactions:</b>		
Cash paid for income taxes	\$ 7	\$ 14

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