August 7, 2024

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

Conference Call and Webcast August 8 at 8:00 AM Eastern Time / 7:00 AM Central Time

- **Acute Ischemic Stroke (AIS) Phase 2/3 ReMEDy2 Trial Interim Enrollment (n=144) Targeted for Q1 2025**
- **Preeclampsia Phase 2 Investigator-sponsored Trial Beginning in Q4 2024 with Proof-of-Concept Results Targeted for First Half 2025**
- **Completed $12 Million Private Placement, Extending 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 June 30, 2024. Management will host a conference call Thursday, August 8, 2024, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and second quarter 2024 financial results.

ReMEDy2 Phase 2/3 AIS Clinical Developments

Progress continues with site activation activities accelerating. As part of this, DiaMedica has selected and prioritized fifteen research centers in the United States that are anticipated to be top enrollment centers. DiaMedica anticipates these top fifteen centers will enroll a disproportionately large share of participants in the study, and at least nine of these centers are expected to be activated this quarter.

With the recent acceleration in site activities the Company reiterates its guidance that full enrollment for the 144 patients for the interim analysis will be completed in the first quarter of 2025.

"Our clinical team is energized by the progress made over the past 90 days and is eager to activate and better support our high-volume centers," stated Dr. Lorianne Masuoka, DiaMedica’s Chief Medical Officer. "We are also pleased to report that there have been no cases of hypotension in newly enrolled participants."

Preeclampsia Program

In June 2024, the Company announced the expansion of the Company’s DM199 clinical development program into preeclampsia (PE). 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. Symptoms may include severe headaches, vision changes, upper abdominal pain and swelling in the hands and face. Delivery of the baby, often very prematurely, is the only available option for stopping the progression of preeclampsia. Additionally, once women have had preeclampsia, they have three to four times the risk of developing high blood pressure and double the risk for heart disease and stroke. Currently, there are no approved therapeutics for PE in the United States or Europe.

DM199 has the potential to lower blood pressure, enhance endothelial health, and improve perfusion to maternal organs and the placenta. The Company has also completed studies on fertility, embryofetal development and pre- and post-natal development in animal models, which support the potential safety in pregnant humans. Additionally, the Company recently completed a placental transfer study in pregnant rats in which DM199 did not cross the placental barrier. Specifically, DM199 was detectable in the maternal blood, but undetectable in the fetal blood.

A Phase 2 PE trial is scheduled to be initiated in the fourth quarter of 2024. The trial is expected to be an open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored study of DM199 for the treatment of PE 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 with the first subject anticipated to be enrolled in the fourth quarter of 2024. Part 1A topline study results are intended to demonstrate initial proof-of-concept results including whether DM199 is safe, lowers blood pressure, dilates intrauterine arteries to increase placental blood flow and several biomarkers and are expected in the first half of 2025.

On July 29, 2024, the Company hosted a Preeclampsia Key Opinion Leader (KOL) Event. A replay of the event is available at **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**.

Private Placement of Common Shares

As previously announced, on June 25, 2024, DiaMedica entered into securities purchase agreements with accredited investors, pursuant to which the Company agreed to issue and sell an aggregate 4,720,000 common shares at a purchase price of $2.50 per share, approximately 10% above DiaMedica’s closing price on June 25, 2024, in a private placement. As a result of the offering, which closed on June 28, 2024, DiaMedica received gross proceeds of $11.8 million. After deducting estimated offering expenses, the Company received net proceeds of approximately $11.7 million.

The Company expects to use the net proceeds from the private placement to continue its clinical and product development activities for DM199, including its pivotal Phase 2/3 ReMEDy2 trial for the treatment of acute ischemic stroke and its clinical expansion into preeclampsia, and for other working capital and general corporate purposes. The financing is expected to extend DiaMedica’s cash runway into the third quarter of 2026.

Balance Sheet and Cash Flow

DiaMedica reported total cash, cash equivalents and investments of $54.1 million, current liabilities of $3.1 million and working capital of $51.9 million as of June 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 increases in cash, cash equivalents and investments and in working capital were due to the net proceeds received from our June 2024 private placement, partially offset by cash used to fund operations in the current year.

Net cash used in operating activities for the six months ended June 30, 2024 was $11.2 million compared to $10.1 million for the six months ended June 30, 2023. The increase in cash used in operating activities was driven primarily by the advance of deposit funds to vendors supporting our ReMEDy2 clinical trial during the current year period.

Financial Results

Research and development (R&D) expenses increased to $3.9 million for the three months ended June 30, 2024, up from $2.5 million for the three months ended June 30, 2023. R&D expenses increased to $7.6 million for the six months ended June 30, 2024, up from $6.2 million for the six months ended June 30, 2023. These increases related to the continuation of the Company's ReMEDy2 clinical trial and increased staffing costs driven by the expansion of its clinical team. These increases were partially offset by cost reductions related to clinical trial work completed in 2023, the Phase 1C and REDUX trials, and the completion in 2023 of in-use study work performed to address the clinical hold on the Company's ReMEDy2 trial.

General and administrative (G&A) expenses were $1.7 million for the three months ended June 30, 2024, down from $2.2 million for the three months ended June 30, 2023. G&A expenses were $3.8 million for the six months ended June 30, 2024, down from $4.1 million for the six months ended June 30, 2023. These decreases resulted from the combination of a reduction in the cost of directors and officers liability insurance premiums and decreased legal fees incurred in connection with the Company's lawsuit against PRA Netherlands, partially offset by increased personnel costs incurred in conjunction with expanding the Company's clinical team and increased non-cash share-based compensation costs.

Other income, net, was $526 thousand and $1.1 million for the three and six months ended June 30, 2024, respectively, compared to $271 thousand and $527 thousand for the three and six months ended June 30, 2023, respectively. These increases were driven by increased interest income recognized during the current year periods related to higher marketable securities balances during the current year periods as compared to the same periods in the prior year.

Conference Call and Webcast Information

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

Date:	Thursday, August 8, 2024
Time:	8:00 AM ET / 7:00 AM CT
Web access:	https://app.webinar.net/RzlwnM9ne8E
Dial In:	(646) 357-8785
Conference ID:	35082

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 August 15, 2024, by dialing (888) 660-6345 (US Toll Free) and entering the replay passcode: 35082#.

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 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 the Preeclampsia Phase 2 Trial

This Phase 2 open-label, single center, single-arm, safety and pharmacodynamic, proof-of-concept, investigator-sponsored study of DM199 in treating preeclampsia will be 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, with the first subject anticipated to be enrolled in the fourth quarter of 2024, pending regulatory approval. Part 1A topline study results are anticipated in the first half of 2025 and are intended to demonstrate whether DM199 is safe, lowers blood pressure, and dilates intrauterine arteries to increase placental blood flow.

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 factor. 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.

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 interim enrollment in the ReMEDy2 trial; timing for commencement and results of the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical benefits and success of DM199; 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, uncertainties relating to risks and uncertainties relating to the planned clinical expansion into preeclampsia and the planned DM199 Phase 2 trial for preeclampsia; 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; 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, 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 June 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 3,928	$ 2,543	$ 7,604	$ 6,161
General and administrative	1,710	2,198	3,775	4,101
Operating loss	(5,638)	(4,741)	(11,379)	(10,262)
Other income:				
Other income, net	526	271	1,123	527
Loss before income tax expense	(5,112)	(4,470)	(10,256)	(9,735)
Income tax expense	(7)	(7)	(14)	(14)
Net loss	(5,119)	(4,477)	(10,270)	(9,749)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(12)	(34)	(57)	11
Net loss and comprehensive loss	$ (5,131)	$ (4,511)	$ (10,327)	$ (9,738)
Basic and diluted net loss per share	$ (0.13)	$ (0.16)	$ (0.27)	$ (0.36)
Weighted average shares outstanding – basic and diluted	38,068,378	27,312,008	38,013,189	26,882,858

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

	June 30, 2024	December 31, 2023
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 14,066	$ 4,543
Marketable securities	39,989	48,352
Prepaid expenses and other assets	568	411
Amounts receivable	391	369
Total current assets	55,014	53,675
Non-current assets:		
Deposits	1,308	—
Operating lease right-of-use asset, net	317	354
Property and equipment, net	152	131
Total non-current assets	1,777	485
Total assets	$ 56,791	$ 54,160
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 759	$ 926
Accrued liabilities	2,229	1,777
Operating lease obligation	85	80
Finance lease obligation	15	3
Total current liabilities	3,088	2,786
Non-current liabilities:		
Operating lease obligation	272	316
Finance lease obligation	16	1
Total non-current liabilities	288	317
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 42,692,582 and 37,958,000 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	—	—
Paid-in capital	179,294	166,609
Accumulated other comprehensive income (loss)	(51)	6
Accumulated deficit	(125,828)	(115,558)
Total shareholders' equity	53,415	51,057
Total liabilities and shareholders' equity	$ 56,791	$ 54,160

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

	Six Months Ended June 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (10,270)	$ (9,749)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	931	802
Amortization of discount on marketable securities	(648)	(432)
Non-cash lease expense	37	34
Depreciation	18	14
Changes in operating assets and liabilities:		
Amounts receivable	(22)	(106)
Prepaid expenses and other assets	(156)	(424)
Deposits	(1,308)	—
Accounts payable	(167)	122
Accrued liabilities	413	(380)
Net cash used in operating activities	(11,172)	(10,119)
Cash flows from investing activities:		
Purchase of marketable securities	(18,047)	(52,743)
Maturities of marketable securities	27,000	27,135
Purchases of property and equipment	(9)	(11)
Net cash provided by (used in) investing activities	8,944	(25,619)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	11,747	36,852
Proceed from the exercise of common stock options	7	—
Principal payments on finance lease obligation	(3)	(3)
Net cash provided by financing activities	11,751	36,849
Net increase in cash and cash equivalents	9,523	1,111
Cash and cash equivalents at beginning of period	4,543	4,728
Cash and cash equivalents at end of period	$ 14,066	$ 5,839
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	$ 30	$ —
Cash paid for income taxes	$ 14	$ 20

View source version on businesswire.com:
https://www.businesswire.com/news/home/20240807302496/en/

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

For Investor Inquiries:
Mike Moyer
Managing Director, LifeSci Advisors, LLC
mmoyer@lifesciadvisors.com

Source: DiaMedica Therapeutics Inc.