

March 14, 2022



# DiaMedica Therapeutics Provides a Business Update and Announces Fourth Quarter 2021 Financial Results

*Conference Call and Webcast March 15 at 8:00 am Eastern Time / 7:00 am Central Time*

- ***Currently Dosing Patients in Pivotal Phase 2/3 ReMEDy2 Acute Ischemic Stroke Trial***
- ***Team Expanded with Addition of Chief Medical Officer and Chief Commercial Officer***
- ***Strong Balance Sheet with \$45M Cash, Runway Into 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 year ended December 31, 2021. Management will host a conference call Tuesday, March 15, 2022, at 8:00AM Eastern Time / 7:00AM Central Time, to discuss its business update and full year financial results.

“Our clinical, regulatory, financial and team building achievements in 2021 have laid a solid foundation for success,” said Rick Pauls, CEO of DiaMedica. “In 2022, our team is focused on executing on our Phase 2/3 ReMEDy2 trial of DM199 in acute ischemic stroke to reach the blinded interim analysis in 2023.”

## ***Pivotal Phase 2/3 ReMEDy Trial of DM199 for Acute Ischemic Stroke Initiated & Building Out Hospital Study Site Network***

The Phase 2/3 ReMEDy2 trial is a randomized, double-blind, placebo-controlled Phase 2/3 adaptive trial designed to enroll 350 patients at approximately 75 sites in the United States. Patients enrolled in the study will be treated with either DM199 or placebo within 24 hours of the onset of acute ischemic stroke (AIS) symptoms. The study excludes patients treated with tissue plasminogen activator (tPA) and those with large vessel occlusions. The study population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the short treatment window of up to 4.5 hours from symptom onset required for administration of tPA.

The ReMEDy2 trial will evaluate the effects of DM199 on both stroke recoveries post AIS, as measured by the well-established modified Rankin Scale (mRS), and the incidence of AIS recurrence at day 90 as two separate, independent, primary endpoints, with each statistically powered for success. Recurrent strokes represent 25% of all ischemic strokes, often occurring in the first few weeks after an initial stroke, and are typically more disabling, costly and fatal than initial strokes. DiaMedica is actively working to open study sites.

## ***DiaMedica Participates in International Stroke Conference and Received Strong Endorsement From Neurologists***

The Company recently exhibited at the American Heart Association's 2022 International Stroke Conference in New Orleans, LA. DiaMedica presented two abstracts at the conference highlighting the beneficial effects of DM199 on stroke recurrence in the Company's ReMEDy1 Phase 2 trial as well as the design of the Company's current pivotal Phase 2/3 ReMEDy2 trial of DM199 in AIS with Scott Kasner, M.D., national principal investigator for the ReMEDy2 trial. DiaMedica also had the opportunity to discuss DM199 and the ReMEDy2 trial with many of the attending neurologists. DiaMedica's Chief Medical Officer, Kirsten Gruis, M.D., commented, "We received encouraging feedback on DM199, its mechanism of improving collateral circulation, its potential benefit for AIS patients and observed safety profile. What is unique about the drug and trial design is that we plan to assess two separate clinically meaningful endpoints, stroke recoveries and prevention of ischemic stroke recurrence, across the same study population giving us potentially two separate endpoints to assess clinical benefit. We are also planning an interim analysis after 40% of patients are enrolled or approximately 140 patients have completed their 90-day follow-up period."

## ***Addition of Chief Medical Officer and Chief Commercial Officer***

DiaMedica recently announced the addition of two key senior executives to the leadership team. Dr. Kirsten Gruis, Chief Medical Officer, is a board-certified neurologist with 20 years of experience in both clinical medicine and drug development in large and small biopharmaceutical companies. Dom Cundari, Chief Commercial Officer, has over thirty years of experience launching innovative products and building and managing commercial organizations in multiple therapeutic areas at Genentech, including Activase<sup>®</sup> for AIS.

## ***Last Patient Dosed in REDUX Phase 2 CKD Basket Trial***

Enrollment in the Phase 2 REDUX basket trial of DM199 in chronic kidney disease (CKD) has been completed as of December 31, 2021. DM199 continues to be generally safe and well tolerated in CKD patients.

The Company expects that the final data will be consistent with the interim data from REDUX which was presented at the American Society of Nephrology's annual Kidney Week meeting in November 2021. Noting that the overall and individual sample sizes are small, the IgA Nephropathy (IgAN) cohort demonstrated a statistically significant geometric mean reduction of 34% in albuminuria in participants with moderate to severe baseline albuminuria. The trial also demonstrated early signals of potential disease modification with the APRIL and IgA1 biomarkers decreasing 35% and 22%, respectively, in all participants, regardless of baseline albuminuria. The hypertensive African American cohort, demonstrated a clinically meaningful geometric mean reduction of over 50% in the patients with moderate to severe baseline albuminuria and large reductions in systolic/diastolic blood pressure levels of -19/-13 mmHg at the 2 µg/kg dose level.

CKD represents an attractive development opportunity for DM199 and the Company is evaluating next steps for this program.

## **Financial Results**

Research and development (R&D) expenses increased slightly to \$8.8 million for the year ended December 31, 2021, up from \$8.2 million in the prior year. This increase was primarily due to a combination of costs incurred for the Company's pivotal Phase 2/3 ReMEDy2 trial and increased personnel costs associated with adding staff to support R&D operations. This increase was partially offset by decreased costs incurred for the Company's earlier ReMEDy1 Phase 2 acute ischemic stroke trial, which completed during 2020, and decreased costs for the REDUX trial, as the number of enrollments in the REDUX trial declined throughout 2021 as the study neared completion.

General and administrative (G&A) expenses were \$4.9 million and \$4.5 million for the years ended December 31, 2021 and 2020, respectively. This increase was due to a number of factors, including increased costs associated with professional services, the payment to Catalent of a milestone obligation under a technology license agreement with Catalent, increased directors and officers liability insurance costs and increased personnel costs to support the Company's expanding clinical programs. These increases were partially offset by reduced non-cash, share-based compensation costs.

### **Balance Sheet and Cash Flow**

As of December 31, 2021, DiaMedica had cash, cash equivalents and marketable securities of \$45.1 million, working capital of \$43.9 million and shareholders' equity of \$44.0 million, compared to \$27.5 million in cash, cash equivalents and marketable securities, \$25.9 million in working capital and shareholders' equity of \$26.0 million as of December 31, 2020. The increases in combined cash, cash equivalents and marketable securities and in working capital are due primarily to the net proceeds from the Company's September 2021 private placement, partially offset by cash used in operating activities during 2021.

Net cash used in operating activities for the year ended December 31, 2021 was \$12.3 million compared to \$9.2 million for the year ended December 31, 2020. This increase relates primarily to the increase in the net loss, partially offset by non-cash share-based compensation and the effects of the changes in operating assets and liabilities.

### **Conference Call and Webcast Information**

DiaMedica Management will host a conference call and webcast to discuss its business update and 2021 financial results on Tuesday, March 15, 2022, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date: Tuesday, March 15, 2022  
Time: 8:00 AM ET / 7:00 AM CT  
Web access: <https://events.g4inc.com/attendee/778628289>  
Dial In: (888) 440-4368  
Conference ID: 4814247

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 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 March 22, 2022, by dialing (800) 770-2030 (US Toll Free) and entering the replay passcode: 4814247.

## **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 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 acute ischemic stroke and patients with chronic kidney disease. In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of acute ischemic stroke.

## **About DiaMedica Therapeutics Inc.**

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering serious diseases. Its 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 (AIS) and chronic kidney disease (CKD). 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 "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 anticipated clinical benefits and success of DM199, the timing and requirements of its clinical programs, including its Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes has the potential to serve as a pivotal registration study of DM199 in that patient population, the potential for each of the two separate independent primary endpoints to be the basis for regulatory approval of DM199 for the treatment of AIS; anticipated site activations, enrollment, clinical results and ability to achieve clinical and other milestones and its goal of offering a treatment option for patients who suffer from AIS. 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 possibility of unfavorable results from DiaMedica's 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 AIS and CKD 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; 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 AIS and CKD, 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. 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>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
Operating expenses:		
Research and development	\$ 8,765	\$ 8,205
General and administrative	4,881	4,494
Total operating expenses	13,646	12,699
Operating loss	(13,646)	(12,699)
Other income:		
Other income, net	82	229
Governmental assistance - research incentives	—	205
Total other income, net	82	434
Loss before income tax expense	(13,564)	(12,265)
Income tax expense	(28)	(27)
Net loss	(13,592)	(12,292)
Other comprehensive loss		
Unrealized loss on marketable securities	(49)	(4)
Net loss and comprehensive loss	\$ (13,641)	\$ (12,296)
Basic and diluted net loss per share	\$ (0.65)	\$ (0.78)
Weighted average shares outstanding – basic and diluted	20,773,399	15,680,320

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

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
	(unaudited)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 4,707	\$ 7,409
Marketable securities	40,405	20,098
Amounts receivable	130	340
Deposits	113	10
Prepaid expenses and other assets	84	64
Total current assets	<u>45,439</u>	<u>27,921</u>
Non-current assets:		
Operating lease right-of-use asset	42	100
Property and equipment, net	70	74
Total non-current assets	<u>112</u>	<u>174</u>
Total assets	<u>\$ 45,551</u>	<u>\$ 28,095</u>
<b>LIABILITIES AND EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 509	\$ 1,099
Accrued liabilities	966	864
Finance lease obligation	4	6
Operating lease obligation	45	59
Total current liabilities	<u>1,524</u>	<u>2,028</u>
Non-current liabilities:		
Finance lease obligation, non-current	3	7
Operating lease obligation, non-current	—	46
Total non-current liabilities	<u>3</u>	<u>53</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 and 18,746,157 shares issued and outstanding, as of December 31, 2021 and December 31, 2020, respectively	—	—
Paid-in capital	126,576	94,925
Accumulated other comprehensive loss	(51)	(2)
Accumulated deficit	(82,501)	(68,909)
Total shareholders' equity	<u>44,024</u>	<u>26,014</u>
Total liabilities and shareholders' equity	<u>\$ 45,551</u>	<u>\$ 28,095</u>

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

	<b>Year Ended December 31,</b>	
	<b>2021</b>	<b>2020</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (13,592)	\$ (12,292)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,558	1,843
Amortization of discount on marketable securities	161	(4)
Non-cash lease expense	58	52
Depreciation	24	21
Changes in operating assets and liabilities:		
Amounts receivable	210	483
Deposits	(103)	78
Prepaid expenses	(20)	(17)
Accounts payable	(590)	917
Accrued liabilities	42	(266)
Net cash used in operating activities	<u>(12,252)</u>	<u>(9,185)</u>
<b>Cash flows from investing activities:</b>		
Purchase of marketable securities	(69,813)	(39,746)
Maturities of marketable securities	49,296	23,643
Purchase of property and equipment	(22)	(47)
Disposition of property and equipment, net	2	16
Net cash used in investing activities	<u>(20,537)</u>	<u>(16,134)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common shares, net of offering costs	29,849	28,805
Proceeds from exercise of stock options	244	45
Principal payments on finance lease obligations	(6)	(5)
Net cash provided by financing activities	<u>30,087</u>	<u>28,845</u>
Net increase (decrease) in cash and cash equivalents	(2,702)	3,526
Cash and cash equivalents at beginning of period	7,409	3,883
Cash and cash equivalents at end of period	<u>\$ 4,707</u>	<u>\$ 7,409</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for income taxes	<u>\$ 28</u>	<u>\$ 36</u>

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Source: DiaMedica Therapeutics Inc.