# **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K

**CURRENT REPORT** Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 17, 2025

# DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

**British Columbia** (State or other jurisdiction of incorporation)

001-36291 (Commission File Number)

Not Applicable (IRS Employer Identification No.)

301 Carlson Parkway, Suite 210 Minneapolis, Minnesota (Address of principal executive offices)

55305

(Zip Code)

(763) 496-5454 (Registrant's telephone number, including area code)

## Not Applicable

(Former name or former address, if changed since last report.)

Ch	eck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Voting common shares, no par value per share	DMAC	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

### Item 2.02. Results of Operations and Financial Condition.

On March 17, 2025, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the year ended December 31, 2024. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and the information set forth therein is incorporated herein by reference and constitutes a part of Item 2.02 of this report.

The information contained in Item 2.02 of this report and Exhibit 99.1 to this report shall not be deemed to be "filed" with the United States Securities and Exchange Commission for purposes of Section 18 of the United States Securities Exchange Act of 1934, as amended (the "Exchange Act"), and shall not be incorporated by reference into any filings made by the Company under the United States Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 17, 2025 providing a business update and announcing full year 2024 financial results (furnished herewith)
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

# SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# DIAMEDICA THERAPEUTICS INC.

By: /s/ Scott Kellen
Scott Kellen
Chief Financial Officer and Secretary

Dated: March 17, 2025



### DiaMedica Therapeutics Provides a Business Update and Announces Full Year 2024 Financial Results

Conference Call and Webcast March 18 at 8:00 AM Eastern Time / 7:00 AM Central Time

- Preeclampsia Phase 2 Trial Preliminary Topline Safety and Efficacy Data from Part 1A of the Study Expected in the Second Quarter of 2025
- Acute Ischemic Stroke Phase 2/3 Program Enrollment Ongoing
- Appointed Experienced Biotech Executive Daniel J. O'Connor to the Board
- Cash Runway into Q3 2026

Minneapolis, Minnesota – March 17, 2025 (Business Wire) – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for acute ischemic stroke and preeclampsia, today provided a business update and financial results for the year ended December 31, 2024. Management will host a conference call Tuesday, March 18, 2025, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and full year 2024 financial results.

"We made significant progress in 2024, advancing our AIS program and expanding into preeclampsia," said Rick Pauls, President and CEO of DiaMedica. "Both of these populations are critically underserved, representing substantial unmet medical needs and large commercial opportunities."

## Preeclampsia Phase 2 Clinical Developments

Dosing in the Phase 2 investigator-sponsored trial of DM199 for preeclampsia (DM199 For Pregnancy Complications trial – NCT06875141) began in November 2024 in South Africa and is ongoing. Multiple dosing cohorts have now been completed. Topline preliminary safety and efficacy data from Part 1A of the study is anticipated in the second quarter of 2025.

## Acute Ischemic Stroke (AIS) ReMEDy2 Phase 2/3 Clinical Developments

The total number of activated study sites has reached 30 hospitals during the first quarter of 2025 for the Company's Phase 2/3 AIS trial (the ReMEDy2 trial -NCT065216). The majority of these sites are operating under version 5.0 of the study protocol, the latest version, which expanded the pool of eligible AIS participants. While the Company has noted an increase in enrollment in the first part of 2025, with delays in site activation during 2024, the transition to version 5.0 of the protocol and slower than expected enrollment, the Company anticipates the interim analysis for sample size re-estimation on the first 200 participants in the first half of 2026; the Company notes this timing is based upon anticipated increased enrollment.

DiaMedica further reports that its data safety monitoring board (DSMB) completed its scheduled safety review of the new intravenous dosing rates implemented upon resumption of the ReMEDy2 trial. Based upon that review, the DSMB concluded that the ReMEDy2 trial should continue without modification. This pre-specified assessment was based on a comprehensive review of safety data from the first twenty (N=20) enrolled participants and no significant safety concerns were identified.

#### Daniel J. O'Connor Appointed to the Board

Mr. O'Connor was appointed to DiaMedica's Board of Directors in February 2025. Most recently Mr. O'Connor served as CEO of Ambrx, where he engineered a turnaround of the company resulting in a \$2 billion acquisition by Johnson & Johnson in 14 months.

## Financial Results Highlights for the Year Ended December 31, 2024

- Cash Position and Runway Cash, cash equivalents, and short-term investments were \$44.1 million as of December 31, 2024, compared to \$52.9 million as of December 31, 2023. Based on its current plans, the Company anticipates its current cash, cash equivalents, and short-term investments will enable the Company to fund its planned clinical studies and support corporate operations into the third quarter of 2026.
- Cash Flows Net cash used in operating activities for the year ended December 31, 2024 was \$22.1 million compared to \$18.7 million for the year ended December 31, 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 Company's ReMEDy2 clinical trial during 2024.
- Research and Development (R&D) R&D expenses were \$19.1 million for the year ended December 31, 2024, compared to \$13.1 million for the year ended December 31, 2023. The increase was due primarily to cost increases resulting from the continuation of the ReMEDy2 clinical trial, the expansion of the clinical team, and increased manufacturing development activity. Partially offsetting this increase were cost reductions related to completion of prior clinical and non-clinical work in 2023. DiaMedica expects its R&D expenses to increase moderately relative to recent prior periods as the Company expands its ReMEDy2 trial globally and continues site activation and enrollment and expands its DM199 clinical development program into preeclampsia.
- General and Administrative (G&A) G&A expenses were \$7.6 million for the year ended December 31, 2024, down from \$8.2 million for the year ended December 31, 2023. The decrease resulted primarily from the combination of decreased legal fees and reductions in directors' and officers' liability insurance premiums.
- Net Loss Net loss was \$24.4 million, or \$0.60 loss per share, for the year ended December 31, 2024, compared to \$19.4 million, or \$0.60 loss per share, for the year ended December 31, 2023.

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

DiaMedica Management will host a conference call and webcast to discuss its business update and full year 2024 financial results on Tuesday, March 18, 2025, at 8:00 AM Eastern Time / 7:00 AM Central Time:

 Date:
 Tuesday, March 18, 2025

 Time:
 7:00 AM CDT / 8:00 AM EDT

 Web access:
 https://app.webinar.net/yzor97w9Nvj

Dial In: (800) 836-8184

Conference ID: 50034

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 March 25, 2025, by dialing (888) 660-6345 (US Toll Free) and entering the replay passcode: 50034#.

# About the Phase 2 Trial of DM199 for Preeclampsia

Preeclampsia (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.

#### About the Phase 2/3 ReMEDy2 Trial of DM199 for Acute Ischemic Stroke

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 300 patients at up to 100 sites globally. The final sample size will be determined based upon the results of an interim analysis of 200 participants, and, if not stopped for futility, may range between 300 and 728 patients, according to a pre-determined statistical plan. 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 basilary 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 ReMEDy2 trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

#### **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 preeclampsia and 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, 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," "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 enrollment in the ReMEDy2 trial increasing substantially as a result of version 5.0 of the study protocol, the timing of the interim analysis on the first 200 participants in the first half of 2026; timing for topline results from Part 1A of the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and acute ischemic stroke; future R&D and G&A expenses, and the Company's cash runway into the 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 enrollment, regulatory applications and related filing and approval timelines; the possibility that enrollment in the ReMEDy2 trial will not increase as anticipated; 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 preeclampsia and acute ischemic stroke 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 hospital and medical facility staffing shortages, increased tariffs 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, 2024 filed with the U.S. Securities and Exchange Commission. 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.

# Contact:

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### For Investor Inquiries:

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# DiaMedica Therapeutics Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share amd per share amounts)

 2024		2022
		2023
\$ 19,057	\$	13,110
 7,624		8,157
26,681		21,267
 (26,681)		(21,267)
 2,267		1,929
2,267		1,929
 (24,414)		(19,338)
(30)		(43)
 (24,444)		(19,381)
17		80
\$ (24,427)	\$	(19,301)
\$ (0.60)	\$	(0.60)
40,404,681		32,566,723
<u>s</u>	7,624 26,681 (26,681) 2,267 2,267 (24,414) (30) (24,444) 17 \$ (24,427) \$ (0.60)	7,624 26,681 (26,681)  2,267 2,267 (24,414)  (30) (24,444)  17  \$ (24,427) \$  \$ (0.60) \$

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

	Decen	December 31, 2024		<b>December 31, 2023</b>	
ASSETS					
Current assets:					
Cash and cash equivalents	\$	3,025	\$	4,543	
Marketable securities		41,122		48,352	
Amounts receivable		236		369	
Prepaid expenses and other assets		227		411	
Total current assets		44,610		53,675	
Non-current assets:					
Deposits		1,308		_	
Operating lease right-of-use asset		279		354	
Property and equipment, net		148		131	
Total non-current assets		1,735		485	
Total assets	\$	46,345	\$	54,160	
LIABILITIES AND EQUITY					
Current liabilities:					
Accounts payable	\$	940	\$	926	
Accrued liabilities		4,347		1,777	
Finance lease obligation		13		3	
Operating lease obligation		90		80	
Total current liabilities		5,390		2,786	
Non-current liabilities:					
Finance lease obligation, non-current		12		1	
Operating lease obligation, non-current		225		316	
Total non-current liabilities		237		317	
Shareholders' equity:					
Common shares, no par value; unlimited authorized; 42,818,660 and 37,958,000 shares issued and outstanding, as of December 31, 2024 and 2023, respectively		_		_	
Paid-in capital		180,697		166,609	
Accumulated other comprehensive income		23		6	
Accumulated deficit		(140,002)		(115,558)	
Total shareholders' equity		40,718		51,057	
Total liabilities and shareholders' equity	\$	46,345	\$	54,160	

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

	Year Ended December 31,		
	20	24	2023
Cash flows from operating activities:			
Net loss	\$	(24,444) \$	(19,381)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share-based compensation		2,085	1,683
Amortization of discounts on marketable securities		(1,343)	(1,223
Non-cash lease expense		75	70
Depreciation		39	30
Changes in operating assets and liabilities:			
Amounts receivable		133	(287
Prepaid expenses and other assets		184	(160
Deposits		(1,308)	_
Accounts payable		14	192
Accrued liabilities		2,489	348
Net cash used in operating activities		(22,076)	(18,728
Cash flows from investing activities:			
Purchase of marketable securities		(50,411)	(69,410
Maturities of marketable securities		59,000	51,135
Purchase of property and equipment		(25)	(24
Net cash provided by (used in) investing activities		8,564	(18,299
Cash flows from financing activities:			
Proceeds from issuance of common shares, net of offering costs		11,747	36,848
Proceeds from the exercise of stock options		256	_
Principal payments on finance lease obligations		(9)	(6
Net cash provided by financing activities		11,994	36,842
Net decrease in cash and cash equivalents		(1,518)	(185
Cash and cash equivalents at beginning of period		4,543	4,728
Cash and cash equivalents at end of period	\$	3,025 \$	4,543
Supplemental disclosure of cash flow information:			
Assets acquired under financing lease	\$	30 \$	_
Cash paid for income taxes	\$	26 \$	33