
**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): **May 13, 2025**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada
(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.)

Check 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. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 13, 2025, DiaMedica Therapeutics Inc. (the “Company”) announced its condensed consolidated financial results for the quarter ended March 31, 2025. 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 May 13, 2025 providing a business update and announcing first quarter 2025 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: May 13, 2025



DiaMedica Therapeutics Reports First Quarter 2025 Financial Results And Provides Business Highlights

Conference Call and Webcast May 14 at 8:00 AM Eastern Time / 7:00 AM Central Time

- **Topline DM199 Preeclampsia Phase 2 Part 1A Proof of Concept Results Expected in Near Term and Phase 2 Part 1B Expected to Initiate in Q3 2025**
- **KOL Event Scheduled for May 28, 2025 to Discuss the Disease of Preeclampsia and the Ongoing DM199 Phase 2 Study Design**
- **Acute Ischemic Stroke Phase 2/3 Program Enrollment Progressing as Planned**
- **Cash Runway into Q3 2026**

Minneapolis, Minnesota – May 13, 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 quarter ended March 31, 2025. Management will host a conference call Wednesday, May 14, 2025, at 8:00 AM Eastern Time / 7:00 AM Central Time to discuss its business update and first quarter 2025 financial results.

Preeclampsia Phase 2 Clinical Developments – Parts 1A and B

Dosing in the Phase 2 Part 1A trial of DM199 for preeclampsia (DM199 For Pregnancy Complications trial –PACTR202404895013782) continues as planned and is nearing the identification of the most clinically-relevant therapeutic dose-level for use in the Part 1B expansion phase of the trial. Preliminary topline safety and efficacy results from Part 1A of the trial are anticipated between the second half of June and the first half of July, depending on turnaround time for laboratory test results.

“With the upcoming release of preliminary topline safety and efficacy results from Part 1A of the Phase 2 preeclampsia study, DiaMedica is entering what we believe will be an exciting phase in the history of our company,” said Rick Pauls, President and CEO of DiaMedica Therapeutics. “Building on this data, we believe DM199 has an opportunity to become a treatment option for preeclampsia, which is among the most underserved conditions in medicine today with no approved therapeutics.”

The Company will be hosting a virtual key opinion leader (KOL) event on May 28, 2025 at 8:00 AM ET to discuss the current treatment landscape for preeclampsia and the clinical trial design and endpoints of the DM199 Phase 2 preeclampsia study. More details to follow in the coming week.

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

Enrollment in the Company's Phase 2/3 ReMEDy2 (the ReMEDy2 trial – NCT065216) trial is progressing as planned as discussed at the Company's last quarterly business update. DiaMedica reiterates its guidance for the interim analysis on the first 200 patients to be completed in the first half of 2026.

Financial Results Highlights for the Quarter Ended March 31, 2025

- **Cash Position and Runway** – Cash, cash equivalents and short-term investments were \$37.3 million as of March 31, 2025, compared to \$44.1 million as of December 31, 2024. 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 quarter ended March 31, 2025 was \$7.1 million compared to \$6.7 million for the same period in 2024. The increase in cash used in operating activities resulted primarily from the increased net loss in the quarter ended March 31, 2025 as compared with the prior year period.
- **Research and Development (R&D)** – R&D expenses were \$5.7 million and \$3.7 million for the quarters ended March 31, 2025 and 2024, respectively. The increase was due primarily to cost increases resulting from the continuation of the ReMEDy2 clinical trial, including its global expansion; increased manufacturing development activity; and the expansion of the clinical team during 2024. These increases were partially offset by cost reductions related to in-use study work performed and completed in the prior year period.
- **General and Administrative (G&A)** – G&A expenses were \$2.5 million and \$2.1 million for the quarters ended March 31, 2025 and 2024, respectively. This increase resulted primarily from additional non-cash share-based compensation.
- **Net Loss** - Net loss was \$7.7 million, or \$0.18 loss per share, for the quarter ended March 31, 2025, compared to \$5.2 million, or \$0.14 loss per share, for the quarter ended March 31, 2024.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and first quarter 2025 financial results on Wednesday, May 14, 2025, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Wednesday, May 14, 2025
Time:	8:00 AM EDT / 7:00 AM CDT
Web access:	https://app.webinar.net/24NpV0mjklG
Dial In:	(800) 836-8184
Conference ID:	93262

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 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 21, 2025, by dialing (888) 660-6345 (US Toll Free) and entering the replay passcode: 93262#.

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. Currently there are no approved pharmacologic treatments of preeclampsia in any marketed territory in the world and represents a critical unmet medical need.

This Phase 2 program is an investigator-sponsored, single center trial evaluating DM199 in preeclampsia that will enroll up to 90 women with preeclampsia and 30 women with fetal growth restriction. This trial 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. The Phase 2 trial consists of three parts:

- Part 1 consists of: Part 1A, an open-label, single-arm, dose-escalation and proof-of-concept study in up to 30 women with preeclampsia requiring delivery within 72 hours. The objective of Part 1A is to identify a clinically-relevant therapeutic dose; Part 1B is an open-label, single-arm, single-dose level, safety, tolerability to then treat an additional up to 30 women with preeclampsia requiring delivery within 72 hours at the dose-level determined in Part 1A.
- Part 2 of the program is an open-label, single-arm, single-dose level, safety and tolerability study treating up to 30 women with preeclampsia undergoing expectant management.
- Part 3 of the program is an open-label, single-arm, single-dose level, safety and tolerability study treating up to 30 women with preeclampsia and fetal growth restriction.

The overall data from the open-label Phase 2 program will enable further detailed discussions with the United States Food and Drug Administration and European regulatory authorities on the appropriate development pathway for market approval.

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 that present within 4.5 to 24 hours of stroke onset. Currently there are no approved pharmacologic agents to treat acute ischemic stroke in the 4.5 to 24 hour timeframe and represents a critical unmet medical need. 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 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 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 preeclampsia and acute ischemic stroke. 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 treatment of preeclampsia, DM199 is intended to lower blood pressure, enhance endothelial health and improve perfusion to maternal organs and the placenta. In the treatment 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.

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 preeclampsia, acute ischemic stroke 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 the timing for preliminary topline safety and efficacy data from Part 1A of the preeclampsia Phase 2 investigator-sponsored trial; continued ReMEDy2 trial enrollment and the timing of the interim analysis on the first 200 participants in the first half of 2026; 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 and topline safety and efficacy data from Part 1A of the Phase 2 trial for preeclampsia and risks and uncertainties relating to the clinical expansion into preeclampsia and that trial; the timing of ReMEDy2 trial enrollment, regulatory applications and related filing and approval timelines; the possibility that enrollment in the ReMEDy2 trial will not continue to increase as anticipated; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; the possibility of unfavorable results from DiaMedica's other 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 preeclampsia and acute ischemic stroke 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 (SEC) and subsequent SEC reports. 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.

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

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 5,656	\$ 3,676
General and administrative	2,488	2,065
Operating loss	(8,144)	(5,741)
Other income, net	443	597
Loss before income tax expense	(7,701)	(5,144)
Income tax expense	(6)	(7)
Net loss	(7,707)	(5,151)
Other comprehensive loss		
Unrealized loss on marketable securities	(18)	(45)
Net loss and comprehensive loss	<u>\$ (7,725)</u>	<u>\$ (5,196)</u>
Basic and diluted net loss per share	<u>\$ (0.18)</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding – basic and diluted	<u>42,843,938</u>	<u>37,958,000</u>

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

	<u>March 31, 2025</u>	<u>December 31, 2024</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,589	\$ 3,025
Marketable securities	33,731	41,122
Prepaid expenses and other assets	649	227
Amounts receivable	253	236
Deposits	200	—
Total current assets	<u>37,422</u>	<u>44,610</u>
Non-current assets:		
Marketable securities	1,000	—
Operating lease right-of-use asset, net	259	279
Property and equipment, net	149	148
Deposits	—	1,308
Total non-current assets	<u>1,408</u>	<u>1,735</u>
Total assets	<u>\$ 38,830</u>	<u>\$ 46,345</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 1,507	\$ 940
Accrued liabilities	3,053	4,347
Operating lease obligation	93	90
Finance lease obligation	12	13
Total current liabilities	<u>4,665</u>	<u>5,390</u>
Non-current liabilities:		
Operating lease obligation	201	225
Finance lease obligation	10	12
Total non-current liabilities	<u>211</u>	<u>237</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 42,859,465 and 42,818,660 shares issued and outstanding, as of		
March 31, 2025 and December 31, 2024, respectively	—	—
Paid-in capital	181,658	180,697
Accumulated other comprehensive income	5	23
Accumulated deficit	(147,709)	(140,002)
Total shareholders' equity	<u>33,954</u>	<u>40,718</u>
Total liabilities and shareholders' equity	<u>\$ 38,830</u>	<u>\$ 46,345</u>

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

	Three Months Ended March 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (7,707)	\$ (5,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	867	488
Amortization of discount on marketable securities	(261)	(329)
Non-cash lease expense	20	18
Depreciation	11	8
Changes in operating assets and liabilities:		
Amounts receivable	(17)	(30)
Prepaid expenses and other assets	(422)	(158)
Deposits	1,108	(1,308)
Accounts payable	567	(210)
Accrued liabilities	(1,315)	19
Net cash used in operating activities	(7,149)	(6,653)
Cash flows from investing activities:		
Purchase of marketable securities	(6,866)	(9,783)
Maturities of marketable securities	13,500	14,000
Purchases of property and equipment	(12)	(9)
Net cash provided by investing activities	6,622	4,208
Cash flows from financing activities:		
Proceeds from the exercise of stock options	94	—
Principal payments on finance lease obligation	(3)	(1)
Net cash provided by (used in) financing activities	91	(1)
Net decrease in cash and cash equivalents	(436)	(2,446)
Cash and cash equivalents at beginning of period	3,025	4,543
Cash and cash equivalents at end of period	<u>\$ 2,589</u>	<u>\$ 2,097</u>
Supplemental disclosure of non-cash transactions:		
Cash paid for income taxes	<u>\$ 6</u>	<u>\$ 7</u>