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): **December 18, 2025**

DIAMEDICA THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

British Columbia	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

301 Carlson Parkway, Suite 210 **Minneapolis, Minnesota**	**55305**
(Address of principal executive offices)	(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 7.01 Regulation FD Disclosure.

On December 18, 2025, DiaMedica Therapeutics Inc. provided a DM199 preeclampsia program update following its pre-IND meeting with the United States Food and Drug Administration (FDA). The text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01 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 DiaMedica under the Securities Act of 1933, as amended, or the Exchange Act, except as may be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

As previously announced, DiaMedica requested and completed an in-person pre-IND meeting with the FDA for a planned study evaluating DM199 in pre-eclampsia. Minutes from the meeting have affirmed the FDA's request for one additional non-clinical, 10-day modified embryo-fetal development (EFD) and pre and postnatal Development (PPND) study in a rabbit model. Preparations for this study have commenced and results are expected to be available by the second quarter of 2026.

Cautionary Note Regarding Forward-Looking Statements

This report 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 report, 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 report include statements regarding expectations regarding the timing for a rabbit treatment study and the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and acute ischemic stroke; and future regulatory requirements. 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 related to the timing and outcomes of non-clinical studies; risks and uncertainties relating to the timing of studies and trials; risks and uncertainties relating to the clinical expansion into preeclampsia and associated trials; 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 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 report represents the expectations of DiaMedica as of the date of this report 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description	Manner of Filing
99.1	Press Release dated December 18, 2025	Furnished Electronically
104	Cover Page Interactive Data File (formatted as inline XBRL)	Filed Electronically

SIGNATURES

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.

Date: December 18, 2025

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

Exhibit 99.1

DiaMedica Therapeutics Provides DM199 Preeclampsia Program Update Following Pre-IND Meeting with FDA

Minneapolis – December 18, 2025 – DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company developing novel treatments for preeclampsia (PE), fetal growth restriction (FGR) and acute ischemic stroke (AIS), today announced completion of a productive in-person pre-IND meeting with the United States Food and Drug Administration (FDA) for a planned study evaluating DM199 in pre-eclampsia. Minutes from the meeting affirmed the FDA's request for one additional non-clinical, 10-day modified embryo-fetal development (EFD) and pre and postnatal Development (PPND) study in a rabbit model. Preparations for this study have commenced, and results are expected to be available by the second quarter of 2026.

"We believe the meeting minutes provide important regulatory clarity on our non-clinical package as we prepare to submit an IND for the study of DM199 in patients with early onset preeclampsia," said Rick Pauls, President and CEO of DiaMedica. "We look forward to ongoing engagement with the FDA as we advance efforts to develop a novel treatment for women suffering from this devastating condition, which is one of the leading causes of maternal and neonatal morbidity and mortality worldwide."

"The ongoing Phase 2 investigator-sponsored trial of DM199 in South Africa has now dosed over 30 women with late-stage PE. Interim data show encouraging safety and efficacy signals, including statistically significant reductions in blood pressure and dilation of intrauterine arteries, and importantly, with no placental transfer of DM199, thereby minimizing unforeseen fetal exposure," said Dr. Julie Krop, Chief Medical Officer of DiaMedica.

About DM199 (rinvecalinase alfa)

DM199 (rinvecalinase alfa) is a recombinant form of human tissue kallikrein-1 (rhKLK1) in clinical development for preeclampsia, fetal growth restriction, 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 factor.

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 preeclampsia, fetal growth restriction 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 DiaMedica's website at www.diamedica.com.

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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 expectations regarding the timing for a rabbit treatment study and the preeclampsia Phase 2 investigator-sponsored trial; anticipated clinical benefits and success of DM199 for the treatment of preeclampsia and acute ischemic stroke; and future regulatory requirements. 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 related to the timing and outcomes of non-clinical studies; risks and uncertainties relating to the timing of studies and trials; risks and uncertainties relating to the clinical expansion into preeclampsia and associated trials; 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 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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