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): **June 21, 2023**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia, Canada	**001-36291**	**Not Applicable**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 8.01 Other Events.

On June 21, 2023, DiaMedica Therapeutics Inc. (the "Company") announced that the U.S. Food and Drug Administration (the "FDA") has removed the clinical hold placed on the investigational new drug application for the Company's ReMEDy2 phase 2/3 clinical trial studying DM199 in the treatment of acute ischemic stroke ("AIS") and that preparations are underway to resume the ReMEDy2 trial as soon as possible. The press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Included in the response to the FDA was a protocol amendment designed to incorporate a reduced dose for the intravenous administration of DM199 and incorporate certain additional measures to reduce the risk of severe hypotension in study participants. In addition, the ReMEDy2 trial now has one primary endpoint of physical recovery from stroke as measured by the well-established modified Rankin Scale (mRS) at day 90. Secondary endpoints for the trial will evaluate, among other things, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity), participant deaths, the National Institute of Health Stroke Score (NIHSS) and Barthel Index stroke scale and the rate of ischemic stroke recurrence through day 90.

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K 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 Current Report on Form 8-K, 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 Current Report on Form 8-K include statements regarding the Company's expectations regarding the timing of its resumption of the ReMEDy2 trial and the anticipated clinical benefits and success of DM199. Such statements and information reflect management's current view and the Company 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 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 the Company'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; the Company's plans to develop, obtain regulatory approval for and commercialize its DM199 product candidate for the treatment of acute ischemic stroke and chronic kidney disease and its expectations regarding the benefits of DM199; the Company'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 the Company's business and clinical trials, including its ability to meet its site activation and enrollment goals; the Company's reliance on collaboration with third parties to conduct clinical trials; the Company'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 acute ischemic stroke and chronic kidney disease, and the risks identified under the heading "Risk Factors" in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2023 and subsequent U.S. Securities and Exchange Commission filings. The forward-looking information contained in this Current Report on Form 8-K represents the Company's expectations as of the date of this Current Report on Form 8-K 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 the Company 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 No.	Description
99.1	Press Release dated June 21 2023 announcing the Removal of the Clinical Hold.
104	The Cover Page from this Current Report on Form 8-K, formatted in Inline XBRL

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.

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

Date: June 21, 2023

DiaMedica Therapeutics Announces that the FDA Has Removed The Clinical Hold On DM199 Phase 2/3 Trial For Ischemic Stroke

Minneapolis, Minnesota – **June 21, 2023 (Business Wire)**– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and kidney diseases, announced today that the U.S. Food and Drug Administration (FDA) has removed the clinical hold placed on the investigational new drug application for its ReMEDy2 phase 2/3 clinical trial studying DM199 in the treatment of acute ischemic stroke (AIS) and that preparations are underway to resume the ReMEDy2 trial as soon as possible.

"We are pleased that the FDA has fully lifted the clinical hold. DM199, a synthetic formulation of the human tissue-1 kallikrein protein (KLK1), represents a novel approach to treating AIS patients, principally aimed at enhancing collateral blood flow in the brain tissues affected by the stroke," said Rick Pauls, DiaMedica's President and CEO.

"We look forward to re-engaging with our study sites and stroke expert principal investigators as we resume our ReMEDy2 trial as there is continued unmet need of new potential therapeutics for patients who have had an ischemic stroke" said Kirsten Gruis, MD, DiaMedica's Chief Medical Officer.

About the 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 (AIS) patients. The trial is intended to enroll approximately 350 patients at 75 sites in the United States. 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. The study population is representative of the approximately 80% of AIS patients who do not have treatment options today, primarily due to the limitations on treatment with tPA 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 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 and clinically studied a recombinant form of the KLK1 protein. The KLK1 protein, produced from the pancreas of pigs 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 (AIS). In September 2021, the FDA granted Fast Track Designation to DM199 for the treatment of AIS.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. is a clinical stage biopharmaceutical company committed to improving the lives of people suffering from serious diseases with a focus on 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 and other vascular diseases. For more information visit the Company's website at www.diamedica.com.

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