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): **October 26, 2022**

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** (Address of principal executive offices)	**55305** (Zip Code)

(763) 312-6755
(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 October 26, 2022, DiaMedica Therapeutics Inc. (the "Company") issued a press release providing an update on the Company's ReMEDy2 Phase 2/3 trial for the treatment of acute ischemic stroke and in connection therewith announced the consolidated balances of its cash and cash equivalents and marketable securities as of September 30, 2022. 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 Securities and Exchange Commission for purposes of Section 18 of the 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 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.

On October 26, 2022, the Company issued a press release providing an update on the Company's ReMEDy2 Phase 2/3 trial for the treatment of acute ischemic stroke. 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.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated October 26, 2022 providing update on ReMEDy2 trial
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: October 26, 2022

Exhibit 99.1

DiaMedica Therapeutics Provides Update on ReMEDy2 Trial

Minneapolis, Minnesota – **October 26, 2022 (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 Company has received further guidance from the U.S. Food and Drug Administration (FDA) regarding the clinical hold on its ReMEDy2 Phase 2/3 trial for the treatment of acute ischemic stroke (AIS). The FDA stated it is maintaining its clinical hold at this time and that additional non-clinical data related to the materials used by a hospital in the intravenous (IV) infusion process is needed to resolve the clinical hold.

In response to the FDA's clinical hold letter in July 2022 related to three serious adverse event cases of transient acute hypotension during intravenous infusion of DM199, the Company previously submitted to the FDA supporting *in vitro* data that the etiology (cause) is likely related to switching the type of IV bag used in the prior ReMEDy 1 trial, where no hypotensive episodes were reported, versus the current ReMEDy 2 trial. Hypotension is a known response to DM199 treatment. Significant differences in protein binding were observed between the two types of IV bags used in the studies that the Company believes altered the total amount of drug being administered. Following review of this data, the FDA requested an additional in-use *in vitro* stability study of the IV administration of DM199 which includes the IV tubing and mechanical infusion pump to further rule out any etiology other than IV bag protein binding. Preparations for these *in vitro* studies are already underway and the Company will request a Type A FDA meeting to confirm the study design and obtain additional guidance towards lifting the clinical hold and resuming the ReMEDy2 trial. The Company plans to provide an update on the timing of completion of the in-use in-vitro study and data submission following consultation with the FDA.

Rick Pauls, DiaMedica's Chief Executive Officer, commented "Patient safety remains our top priority. We believe that we now have a clear path to resolving the clinical hold and we are highly focused on resuming the ReMEDy2 trial as quickly as possible."

The FDA placed a clinical hold on the Company's Phase 2/3 ReMEDy2 trial following the Company voluntarily pausing patient enrollment in the trial to investigate three unexpected instances of clinically significant hypotension (low blood pressure) occurring shortly after initiation of IV dose of DM199. The hypotension was transient and blood pressure levels of all three patients recovered back to baseline within minutes of stopping the infusion and the patients suffered no ongoing adverse effects.

DiaMedica's cash, cash equivalents and marketable securities as of September 30, 2022 were $36.1 million resulting in a cash burn of $2.3 million for the third quarter of 2022, down from a cash burn of $2.6 million in the second quarter of 2022, reflecting steps taken by the Company to conserve capital during the clinical hold.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its ReMEDy2 update on Thursday, October 27, 2022, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Thursday, October 27, 2022
Time:	8:00 AM ET / 7:00 AM CT
Web access:	https://events.q4inc.com/attendee/223964256
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 November 3, 2022, by dialing (800) 770-2030 (US Toll Free) and entering the replay passcode: 4814247.

About 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 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 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 (AIS) and patients with chronic kidney disease. 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. DiaMedica's 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 and chronic kidney disease. 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 "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 Company's expectations regarding its ability to resolve the clinical hold imposed by the FDA and its belief that the issues raised by the FDA are potentially addressable, the resumption of the ReMEDy2 trial, and the anticipated clinical benefits and success of DM199, including being a potentially life changing drug to stroke patients. 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 risk that the Company may not know the cause of the hypotension events that occurred in the ReMEDy2 trial or that its plan to resolve the issues and prevent future events may not be successful; the risk that the Company may not be able to address successfully the concerns identified by the FDA or may require the Company to collect additional data or information beyond what the FDA has currently requested and what the Company currently expects; the Company's ability to successfully engage with the FDA and satisfactorily respond to requests from the FDA for further information and data regarding the ReMEDy2 trial and the timing and outcome of the Company's planned interactions with the FDA concerning the clinical hold on the ReMEDy2 trial; the risk that the Company may not be able to lift the clinical hold or do so in a timely manner; uncertainties relating to regulatory applications and related filing and approval timelines, including the risk that FDA may not remove the clinical hold on the ReMEDy2 trial; the possibility of additional future adverse events associated with or unfavorable results from the ReMEDy2 trial; 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 acute ischemic stroke and chronic kidney disease 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, 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 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 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, including its quarterly report on Form 10-Q for the quarterly period ended June 30, 2022. 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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