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 5, 2021**

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.)

Two Carlson Parkway, Suite 260 **Minneapolis, Minnesota**	**55447**
(Address of principal executive offices)	(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 May 5, 2021, DiaMedica Therapeutics Inc. (the “Company”) announced its consolidated financial results for the three months ended March 31, 2021. 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 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	Press Release dated May 5, 2021 providing a business update and reporting first quarter 2021 financial results (furnished herewith)

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 5, 2021

Exhibit 99.1

DiaMedica Therapeutics Provides a Business Update and Announces First Quarter 2021 Financial Results

- ***Investigational New Drug (IND) Application Submitted for Phase 2/3 AIS Study***
- ***Plan to Initiate Phase 2/3 AIS Trial in Summer 2021***
- ***REDUX Phase 2 Diabetic Kidney Disease Cohort Readout Expected in Q2 2021***
- ***Cash Runway Through Mid-2022***

Minneapolis, Minnesota – **May 5, 2021 (Business Wire)**– DiaMedica Therapeutics Inc. (Nasdaq: DMAC), a clinical-stage biopharmaceutical company focused on developing novel treatments for neurological disorders and kidney diseases, today provided a business update and financial results for the quarter ended March 31, 2021. DiaMedica will host a conference call Thursday, May 6, 2021, at 7:00 a.m. Central Time to discuss its business update and first quarter financial results.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

- IND Submitted
- Initiation of Phase 2/3 Trial of DM199 in AIS in Summer 2021

DiaMedica has submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for an adaptive Phase 2/3 clinical trial of DM199, the Company's recombinant form of human tissue kallikrein-1 being developed as a treatment for acute ischemic stroke (AIS) patients. The proposed trial of DM199 is for AIS patients who do not receive tissue plasminogen activator (tPA) and do not have large vessel occlusions, a group that represents up to 80% of all AIS patients. DiaMedica believes that the proposed trial has the potential to serve as a pivotal registration study of DM199 in this patient population.

The FDA has confirmed its receipt of the IND and DiaMedica expects the FDA to complete its regulatory review of the IND by mid-May. If authorized by the FDA, the Company anticipates initiating the study this summer. DiaMedica has selected a contract research organization to assist with the conduct of the study and is actively working to identify, qualify and engage clinical study sites—the expected pacing item for initiation of the study.

The clinical trial is proposed to be a double blinded, placebo controlled, randomized study of approximately 350 participants, based on a 90% powering for statistical significance on the primary endpoint of modified Rankin Scale (mRS) at day 90. Secondary endpoints will include stroke recurrence, mRS shift, NIHSS and Barthel Index, deaths, safety and tolerability measures, and biomarkers relating to KLK1. Independent of this study, the Company plans to discuss with the FDA a second study for the evaluation of the efficacy of DM199 in reducing stroke recurrence based upon the statistically significant reduction in severe recurrent strokes observed in its ReMEDy Phase 2 AIS trial.

“We are pleased with the overall progress of our AIS program,” commented Rick Pauls, Chief Executive Officer of DiaMedica. “We look forward to initiation of this trial and moving closer to potentially providing stroke patients and physicians a much-needed new treatment option for AIS.”

DM199 for the Treatment of Chronic Kidney Disease

- Data Read-out Expected in Q2 2021 on CKD Caused by Type II Diabetes Cohort
- Enrollment Continues in IgA Nephropathy and CKD in African Americans with Hypertension

DiaMedica’s Phase 2 REDUX trial is a multi-center, open-label, investigation to assess the safety and efficacy of multiple doses of DM199, administered over 90 days, in participants with chronic kidney disease (CKD) (Stage 2 or 3) targeting enrollment of approximately 90 participants in three equal Cohorts. Cohort 1 of the study is focused on non-diabetic African Americans with hypertension, a group that is at greater risk for CKD than Caucasians. Additionally, the study is designed to identify African American participants with the APOL1 gene mutation as an exploratory biomarker as these individuals have an even higher risk of developing CKD. Cohort 2 of the study is focused on participants with IgA Nephropathy (IgAN) which is found more commonly in Asians, Caucasians and people of Eastern Europe and is very rare in Blacks and people of African descent and Cohort 3 includes participants with diabetic kidney disease (DKD) which is defined by elevated urine albumin excretion and/or reduced glomerular filtration rate (GFR) – is a serious complication that occurs in 20% to 40% of all diabetics.

As of April 30, 2021, DiaMedica had enrolled a total of 70 subjects, including a fully enrolled DKD Cohort, and approximately 70% of the IgAN and 60% of the African American Cohorts. The Company has continued to experience slower than expected enrollment in the first two Cohorts of the REDUX trial due to the COVID-19 pandemic. However, with the significant declines in new COVID-19 cases and the anticipated availability and effectiveness of vaccines, the Company currently anticipates completion of Cohort 1 and Cohort 2 in the second half of 2021. Preliminary topline results from the DKD Cohort are expected to be available in the second quarter of 2021.

Financial Results

Research and development (R&D) expenses were $2.4 million for the three months ended March 31, 2021, compared with $1.4 million for the three months ended March 31, 2020, an increase of $1.0 million. The increase was due to a number of factors including a year-over-year increase in costs incurred for the REDUX Phase 2 CKD study, and costs associated with an increase in staff levels, consulting services and non-clinical testing required to support preparation for the ReMEDy2 Phase 2/3 stroke study. These increases were partially offset by a year-over-year decrease in costs incurred for the ReMEDy Phase 2 stroke study which completed during 2020.

General and administrative (G&A) expenses were $1.2 million for the three months ended March 31, 2021, up from $1.1 million for the three months ended March 31, 2020. The increase in G&A expenses resulted primarily from increased directors and officers liability insurance, personnel and non-cash share-based compensation costs.

Balance Sheet and Cash Flow

The Company had cash, cash equivalents and marketable securities of $23.4 million, current liabilities of $1.2 million and working capital of $23.0 million as of March 31, 2021, compared to $27.5 million in cash, cash equivalents and marketable securities, $2.0 million in current liabilities and $25.9 million in working capital as of December 31, 2020. The decreases in combined cash, cash equivalents and marketable securities and in working capital are due primarily to increased clinical study costs related to the REDUX Phase 2 CKD study and costs associated with preparing for the ReMEDy2 Phase 2/3 stroke study.

Net cash used in operating activities for the three months ended March 31, 2021 was $4.3 million compared to $3.0 million for the three months ended March 31, 2020. This increase relates primarily to the increase in the net loss, partially offset by the effects of the changes in operating assets and liabilities.

Conference Call Information

DiaMedica Management will host a conference call to discuss its business update and first quarter 2021 financial results on Thursday, May 6, 2021, at 7:00 a.m. Central Time:

Date:	Thursday, May 6, 2021
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://event.on24.com/wcc/r/3081283/E7DD7636B9914C65BD79123196FDA60B
Dial In:	(866) 393-4306 (domestic)
	(734) 385-2616 (international)
Conference ID:	2966016

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 May 13, 2021, by dialing (855) 859-2056 (US Toll Free), (404) 537-3406 (International), and entering the replay passcode: 2966016.

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 chronic kidney disease, retinopathy, stroke, vascular dementia, and resistant hypertension where current treatment options are limited or ineffective. DiaMedica is the first company to have developed 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 Korea for decades. DM199 is currently being studied in patients with chronic kidney disease and patients with acute ischemic stroke.

About DiaMedica Therapeutics Inc.

DiaMedica Therapeutics Inc. (Nasdaq: DMAC) is a clinical stage biopharmaceutical company focused on developing novel treatments to improve the lives of patients with neurological and chronic kidney diseases. To learn more about DiaMedica, visit 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," "look forward," "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 anticipated clinical benefits and success of DM199, the timing and requirements of its clinical programs, including its anticipated Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes will commence in Summer 2021 after an FDA review completion in mid-May and has the potential to serve as a pivotal registration study of DM199 in that patient population, and enrollment, clinical results and ability to achieve clinical milestones, including the timing of completion of enrollment and readout of results in its REDUX trial, and cash runway timing. 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 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 AIS and CKD and its expectations regarding the benefits of DM199; DiaMedica's ability to conduct successful clinical testing of DM199 and within its anticipated parameters, costs and timeframes; the perceived benefits of DM199 over existing treatment options; the potential direct or indirect impact of the COVID-19 pandemic on DiaMedica's business; 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 AIS and CKD, 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, 2020. 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.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	2,406	1,349
General and administrative	1,213	1,055
Operating loss	(3,619)	(2,404)
Other (income) expense:		
Governmental assistance - research incentives	—	(115)
Other (income) expense, net	(4)	127
Total other (income) expense, net	(4)	12
Loss before income tax expense	(3,615)	(2,416)
Income tax expense	7	9
Net loss	(3,622)	(2,425)
Other comprehensive income (loss)		
Unrealized gain (loss) on marketable securities	(2)	40
Net loss and comprehensive loss	$ (3,624)	$ (2,385)
Basic and diluted net loss per share	$ (0.19)	$ (0.19)
Weighted average shares outstanding – basic and diluted	18,766,656	13,107,725

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,329	$ 7,409
Marketable securities	20,072	20,098
Amounts receivable	337	340
Prepaid expenses and other assets	457	74
Total current assets	24,195	27,921
Non-current assets:		
Operating lease right-of-use asset	86	100
Property and equipment, net	75	74
Total non-current assets	161	174
Total assets	$ 24,356	$ 28,095
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$ 689	$ 1,099
Accrued liabilities	420	864
Finance lease obligation	6	6
Operating lease obligation	63	59
Total current liabilities	1,178	2,028
Non-current liabilities:		
Finance lease obligation, non-current	5	7
Operating lease obligation, non-current	28	46
Total non-current liabilities	33	53
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 18,786,157 and 18,746,157 shares issued and outstanding, as of March 31, 2021 and December 31, 2020, respectively	—	—
Paid-in capital	95,680	94,925
Accumulated other comprehensive income	(4)	(2)
Accumulated deficit	(72,531)	(68,909)
Total shareholders' equity	23,145	26,014
Total liabilities and shareholders' equity	$ 24,356	$ 28,095

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (3,622)	$ (2,425)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	511	393
Amortization of discount on marketable securities	26	(14)
Non-cash lease expense	14	13
Depreciation	6	6
Changes in operating assets and liabilities:		
Amounts receivable	3	(162)
Prepaid expenses and other assets	(383)	(397)
Accounts payable	(410)	262
Accrued liabilities	(458)	(654)
Net cash used in operating activities	(4,313)	(2,978)
Cash flows from investing activities:		
Purchase of marketable securities	(11,923)	(8,799)
Maturities of marketable securities	11,921	3,500
Purchases of property and equipment	(9)	(2)
Proceeds from disposition of property and equipment	2	—
Net cash used in investing activities	(9)	(5,301)
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	—	7,682
Proceeds from the exercise of stock options	244	16
Principal payments on finance lease obligations	(2)	(2)
Net cash provided by financing activities	242	7,696
Net decrease in cash and cash equivalents	(4,080)	(583)
Cash and cash equivalents at beginning of period	7,409	3,883
Cash and cash equivalents at end of period	$ 3,329	$ 3,300