

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): **November 10, 2021**

DIAMEDICA THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

British Columbia
(State or other jurisdiction
of incorporation)

001-36291
(Commission
File Number)

Not Applicable
(IRS Employer
Identification No.)

Two Carlson Parkway, Suite 260
Minneapolis, Minnesota
(Address of principal executive offices)

55447
(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 November 10, 2021, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the three and nine months ended September 30, 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 November 10, 2021 providing a business update and reporting third quarter 2021 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: November 10, 2021



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

Conference Call and Webcast November 11 at 8:00 am Eastern Time / 7:00 am Central Time

- *First Patient Dosed in Phase 2/3 ReMEDy2 Acute Ischemic Stroke Trial*
- *Fast Track Designation Granted to DM199 for the Treatment of Acute Ischemic Stroke*
- *FDA Accepts ReMEDy2 Protocol Amendment Elevating Stroke Recurrence to Primary Endpoint*
- *Balance Sheet Strengthened with \$30 Million Private Placement*

Minneapolis, Minnesota – November 10, 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 September 30, 2021. Management will host a conference call Thursday, November 11, 2021, at 7:00AM Central Time/8:00AM Eastern Time to discuss its business update and third quarter financial results.

Pivotal Phase 2/3 ReMEDy Trial of DM199 for Acute Ischemic Stroke Initiated & First Patient Dosed

The Company previously announced the initiation of the first site and today announced dosing of the first patient for its pivotal ReMEDy2 trial. The ReMEDy2 trial is a randomized, double-blind, placebo-controlled Phase 2/3 adaptive trial intended to enroll approximately 350 patients. Patients enrolled in the study will be treated with either DM199 or placebo within 24 hours of the onset of acute ischemic stroke (AIS) symptoms. The trial is studying AIS in a patient population for whom thrombolysis and/or a catheter-based procedure, mechanical thrombectomy, are not medically appropriate or available due to constraints of clot location, comorbidity risks or time from estimated onset of stroke, which represents approximately 80% of all AIS patients.

Also as previously announced, the U.S. Food and Drug Administration (FDA) has accepted the Company's protocol amendment to evaluate the effects of DM119 on the rate of recurrent AIS as a second, independent, primary endpoint. The FDA's acceptance of the amendment allows the Company to evaluate the effects of DM199 on both stroke recoveries post AIS, as measured by the well-established modified Rankin Scale (mRS), and the incidence of AIS recurrence at day 90 as two separate, independent, primary endpoints, with each statistically powered for success. Recurrent strokes represent 25% of all ischemic strokes, often occur in the first few weeks after an initial stroke, and are typically more disabling, costly, and fatal than initial strokes. The Company further notes that there are no changes in treatment, duration, or study population of the trial as part of this protocol amendment.

Secondary endpoints for the study will evaluate participant deaths, mRS shift (which shows the treatment effect on participants across the full spectrum of stroke severity) and additional standard stroke scores (NIHSS and Barthel Index scores).

Fast Track Designation Granted to DM199 for Treatment of Acute Ischemic Stroke

The FDA granted Fast Track Designation to the Company's lead candidate DM199 for the treatment of AIS. Fast Track is a process intended to facilitate the development and expedite the review of investigational drugs for the treatment of serious or life-threatening conditions where there is a significant unmet medical need. Drugs that receive Fast Track Designation may be eligible for more frequent communications and meetings with the FDA to review the drug's development plan, including the design of the proposed clinical trials, use of biomarkers, and the extent of data needed for approval. Drugs with Fast Track Designation may also qualify for accelerated and priority review of new drug applications if relevant criteria are met.

Additional Interim Data From REDUX Phase 2 CKD Study for IgAN Presented at the ASN Kidney Week 2021 Virtual Conference

Additional data from the Company's Phase 2 REDUX trial of DM199 in chronic kidney disease (CKD) was presented at the American Society of Nephrology's (ASN) annual Kidney Week meeting taking place during the first week of November 2021. In the IgA Nephropathy (IgAN) cohort, in addition to continuing to show statistically significant reductions (over 30% decrease) in albuminuria in participants with moderate to severe baseline albuminuria, also demonstrated early signals of potential disease modification with the APRIL and IgA1 biomarkers decreasing 35% and 22%, respectively.

Balance Sheet Strengthened with \$30 Million Private Placement

In September 2021, the Company issued and sold in a private placement an aggregate 7,653,060 common shares at a purchase price of \$3.92 per share to ten accredited investors, resulting in gross proceeds of \$30.0 million and net proceeds of \$29.9 million, after deducting offering expenses.

"We are pleased that our regulatory interactions have led to acceptance of the protocol with the FDA and the Fast Track Designation status which will give the continued focus that this trial deserves given the unmet medical need," said Rick Pauls, DiaMedica's President and Chief Executive Officer. "We believe that we are well positioned to advance toward our goal of offering a treatment option for the millions of patients around the world who suffer from a stroke and need a better chance to recover and avoid recurrent strokes."

Financial Results

Research and development (R&D) expenses increased slightly to \$2.3 million for the three months ended September 30, 2021, up from \$2.2 million for the three months ended September 30, 2020. R&D expenses increased to \$6.9 million for the nine months ended September 30, 2021, compared to \$5.1 million for the nine months ended September 30, 2020, an increase of \$1.8 million. The increase for the nine month comparison was primarily due to a number of factors including costs incurred for the Company's pivotal ReMEDy2 clinical study, increased year-over-year costs related to manufacturing process development and increased personnel costs associated with adding staff to support R&D operations. These increases were partially offset by decreased costs incurred for the earlier ReMEDy Phase 2 stroke study, which completed in the prior year, and the REDUX study as the number of enrollments declined in the later stages of the study.

General and administrative (G&A) expenses were \$1.1 million for the three months ended September 30, 2021, down from \$1.2 million for the three months ended September 30, 2020. G&A expenses increased to \$3.5 million for the nine months ended September 30, 2021, up \$0.2 million from \$3.3 million for the nine months ended September 30, 2020. The increase for the nine month comparison was primarily due to increased professional services costs and increased personnel costs to support the Company's expanding clinical programs. These increases were partially offset by reduced non-cash, share based compensation costs.

Balance Sheet and Cash Flow

As of September 30, 2021, DiaMedica had cash, cash equivalents and marketable securities of \$48.1 million, working capital of \$46.9 million and shareholders' equity of \$47.0 million, compared to \$27.5 million in cash, cash equivalents and marketable securities, \$25.9 million in working capital and shareholders' equity of \$26.0 million as of December 31, 2020. The increases in combined cash, cash equivalents and marketable securities and in working capital are due primarily to the net proceeds from the Company's September 2021 private placement offering, partially offset by operating costs incurred during the quarter.

Net cash used in operating activities for the nine months ended September 30, 2021, was \$9.4 million compared to \$6.2 million for the nine months ended September 30, 2020. This increase relates primarily to the increase in the net loss, partially offset by non-cash share-based compensation and the effects of the changes in operating assets and liabilities.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and third quarter 2021 financial results on Thursday, November 11, 2021, at 7:00AM Central Time:

Date:	Thursday, November 11, 2021
Time:	7:00 AM CT / 8:00 AM ET
Web access:	https://events.q4inc.com/attendee/250819405
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 18, 2021, by dialing (800) 770-2030 (US Toll Free) and entering the replay passcode: 4814247.

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 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 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 serious diseases. Its 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 (AIS) and chronic kidney disease (CKD). Based on promising early clinical results, DiaMedica has initiated and commenced enrollment in its ReMEDy Phase 2/3 trial in the treatment of AIS and is completing enrollment in its REDUX Phase 2 trial for the treatment of certain rare and significant unmet causes of CKD. For more information visit our 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," "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 Phase 2/3 trial for DM199 in patients with AIS, which DiaMedica believes has the potential to serve as a pivotal registration study of DM199 in that patient population, the potential for each of the two separate independent primary endpoints to be the basis for regulatory approval of DM199 for the treatment of AIS; anticipated site activations, enrollment, clinical results and ability to achieve clinical and other milestones in the coming quarters and its goal of offering a treatment option for patients who suffer from AIS. 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, 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; 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 and subsequent U.S. Securities and Exchange Commission filings. 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 2,332	\$ 2,158	\$ 6,894	\$ 5,108
General and administrative	1,084	1,161	3,506	3,323
Operating loss	(3,416)	(3,319)	(10,400)	(8,431)
Other (income) expense:				
Governmental assistance - research incentives	-	(25)	-	(205)
Other (income) expense, net	27	(103)	(75)	(154)
Total other (income) expense	27	(128)	(75)	(359)
Loss before income tax expense	(3,443)	(3,191)	(10,325)	(8,072)
Income tax expense	7	2	21	20
Net loss	(3,450)	(3,193)	(10,346)	(8,092)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(2)	(19)	(3)	8
Net loss and comprehensive loss	\$ (3,452)	\$ (3,212)	\$ (10,349)	\$ (8,084)
Basic and diluted net loss per share	\$ (0.18)	\$ (0.19)	\$ (0.55)	\$ (0.55)
Weighted average shares outstanding – basic and diluted	19,035,713	16,689,074	18,863,829	14,652,749

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

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 16,219	\$ 7,409
Marketable securities	31,878	20,098
Amounts receivable	104	340
Prepaid expenses and other assets	336	74
Total current assets	<u>48,537</u>	<u>27,921</u>
Non-current assets:		
Operating lease right-of-use asset	57	100
Property and equipment, net	70	74
Total non-current assets	<u>127</u>	<u>174</u>
Total assets	<u>\$ 48,664</u>	<u>\$ 28,095</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 699	\$ 1,099
Accrued liabilities	861	864
Finance lease obligation	4	6
Operating lease obligation	60	59
Total current liabilities	<u>1,624</u>	<u>2,028</u>
Non-current liabilities:		
Finance lease obligation, non-current	4	7
Operating lease obligation, non-current	—	46
Total non-current liabilities	<u>4</u>	<u>53</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,439,217 and 18,746,157 shares issued and outstanding, as of September 30, 2021 and December 31, 2020, respectively	—	—
Paid-in capital	126,296	94,925
Accumulated other comprehensive loss	(5)	(2)
Accumulated deficit	(79,255)	(68,909)
Total shareholders' equity	<u>47,036</u>	<u>26,014</u>
Total liabilities and shareholders' equity	<u>\$ 48,664</u>	<u>\$ 28,095</u>

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (10,346)	\$ (8,092)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	1,260	1,337
Amortization of premium (discount) on marketable securities	51	(24)
Non-cash lease expense	43	39
Depreciation	18	16
Changes in operating assets and liabilities:		
Amounts receivable	236	488
Prepaid expenses and other assets	(262)	(13)
Accounts payable	(400)	538
Accrued liabilities	(48)	(458)
Net cash used in operating activities	<u>(9,448)</u>	<u>(6,169)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(47,740)	(25,048)
Maturities of marketable securities	35,905	8,249
Purchases of property and equipment	(15)	(2)
Proceeds from disposition of property and equipment	2	—
Net cash used in investing activities	<u>(11,848)</u>	<u>(16,801)</u>
Cash flows from financing activities:		
Proceeds from issuance of common shares, net of offering costs	29,867	28,872
Proceeds from the exercise of stock options	244	16
Principal payments on finance lease obligations	(5)	(4)
Net cash provided by financing activities	<u>30,106</u>	<u>28,884</u>
Net increase in cash and cash equivalents	8,810	5,914
Cash and cash equivalents at beginning of period	7,409	3,883
Cash and cash equivalents at end of period	<u>\$ 16,219</u>	<u>\$ 9,797</u>