
**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): **August 10, 2022**

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 August 10, 2022, DiaMedica Therapeutics Inc. (the "Company") announced its consolidated financial results for the three and six-month periods ended June 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 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 10, 2022 providing a business update and reporting second quarter 2022 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: August 10, 2022



DiaMedica Therapeutics Provides a Business Update and Announces Second Quarter 2022 Financial Results

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

- *Company Confident in Plan to Resolve Issues that Led to Clinical Hold of Phase 2/3 ReMEDy2 Trial*
- *Proposal to Resume Trial Will be Submitted to FDA in September*
- *Cash Runway Into 2024*

Minneapolis, Minnesota – August 10, 2022 (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 released financial results for the quarter ended June 30, 2022. DiaMedica will host a conference call on Thursday, August 11, 2022, at 8:00AM Eastern Time / 7:00AM Central Time, to discuss its business update and second quarter financial results.

Clinical Developments

DM199 for the Treatment of Acute Ischemic Stroke

As previously announced, the U.S. Food and Drug Administration (FDA) placed a clinical hold on the Company's Phase 2/3 ReMEDy2 trial for the treatment of acute ischemic stroke (AIS). The clinical hold was issued 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 the intravenous (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.

After pausing enrollment, the Company immediately initiated an investigation and conducted a comprehensive analysis to determine the likely cause of the hypotensive events. The Company learned that these adverse events likely resulted from changing to a new formulation of IV bag in the ReMEDy2 trial, as compared to the IV bag used in the prior, Australian ReMEDy1 trial, which was not readily available at many U.S. study sites. Recent testing of the prior IV bag has shown that as much as half of the DM199 protein bound to the IV bag used in the prior trial. Whereas, the DM199 protein does not bind to the current IV bag. This effectively increased the dose of DM199 delivered to patients in the current trial as compared to the prior trial. DiaMedica notes that hypotension is a known response to KLK1 therapy and that DiaMedica's prior safety studies revealed orthostatic hypotension as the dose limiting tolerability for DM199.

DiaMedica plans to submit this data and its proposed modifications to the study protocol to the FDA in September requesting a removal of the clinical hold. The Company's proposal will include utilizing a reduced IV dose level that will be comparable to the delivered dose that was well tolerated in the 46 patients in the previous ReMEDy1 trial. Although DiaMedica is confident that this change will sufficiently mitigate the risk of clinically significant hypotension in future ReMEDy2 trial patients, no assurance can be provided that it will or that the FDA will release the clinical hold in response to the Company's submission. The FDA will have up to 30 days to respond to DiaMedica's request to lift the clinical hold.

DM199 for the Treatment of Chronic Kidney Disease

DiaMedica continues to work toward completing the study close-out and the final data analysis for its completed REDUX trial studying the use of DM199 for the treatment of chronic kidney disease (CKD) and preparation of plans for next steps while maintaining Company focus on the ReMEDy2 AIS clinical program.

Balance Sheet and Cash Flow

DiaMedica reported total cash and investments of \$38.4 million, current liabilities of \$1.5 million and working capital of \$37.6 million as of June 30, 2022, compared to total cash and investments of \$45.1 million, \$1.5 million in current liabilities and \$43.9 million in working capital as of December 31, 2021. The decreases in cash and investments and in working capital were due primarily to cash used to fund operating activities during the six months ended June 30, 2022.

Net cash used in operating activities was \$6.4 million for each of the six months ended June 30, 2022 and June 30, 2021. Cash used in operating activities is driven primarily by the Company's net loss, partially offset by non-cash share-based compensation and the effects of the changes in operating assets and liabilities.

Financial Results

Research and development (R&D) expenses were \$2.0 million for the three months ended June 30, 2022, down \$0.2 million from \$2.2 million for the three months ended June 30, 2021. R&D expenses decreased to \$3.9 million for the six months ended June 30, 2022, compared to \$4.6 million for the six months ended June 30, 2021, a decrease of \$0.7 million. This decrease for the six-month comparison was due to a number of factors including reduced costs incurred in the current year for wrap-up related activities for the REDUX Phase 2 CKD trial, decreased non-clinical testing costs which were incurred at greater levels in 2021 in preparation for the Phase 2/3 ReMEDy2 trial which initiated during 2021 and decreased manufacturing process development costs. These decreases were partially offset by current year ramp-up of costs incurred in performing the ReMEDy2 trial and increased personnel costs associated with R&D operations.

General and administrative (G&A) expenses were \$1.4 million for the three months ended June 30, 2022, up from \$1.2 million for the three months ended June 30, 2021. G&A expenses increased to \$3.0 million for the six months ended June 30, 2022, compared to \$2.4 million for the six months ended June 30, 2021, an increase of \$0.6 million. The increase for the six-month comparison was primarily due to increased directors' and officers' liability insurance and personnel and professional services costs to support the Company's expanding clinical programs. These increases were partially offset by a reduction in non-cash share-based compensation.

Conference Call and Webcast Information

DiaMedica Management will host a conference call and webcast to discuss its business update and second quarter 2022 financial results on Thursday, August 11, 2022, at 8:00 AM Eastern Time / 7:00 AM Central Time:

Date:	Thursday, August 11, 2022
Time:	8:00 AM ET / 7:00 AM CT
Web access:	https://events.q4inc.com/attende/328637791
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 August 18, 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.

The ReMEDy2 trial has two separate, independent, primary endpoints based upon both the results observed in the first ReMEDy1 phase 2 trial and published results from the urine-derived form of KLK1 used to successfully treat AIS in China. ReMEDy2 is powered for success with either endpoint: 1) physical recovery from stroke as measured by the well-established modified Rankin Scale (mRS) at day 90, and 2) the rate of ischemic stroke recurrence through day 90. Recurrent strokes represent 25% of all ischemic strokes, often occurring in the first few weeks after an initial stroke and are typically more disabling, costly, and fatal than initial strokes.

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 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 DiaMedica's belief as to the cause of the hypotension events, its response to prevent future such events, its anticipated timing for submitting a response to the FDA and its ability to lift the clinical hold in a timely manner or at all; 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, and 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; and its cash runway into 2024. 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 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 in the clinical hold letter or may require the Company to collect additional data or information beyond what it currently expects; 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 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, 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 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, 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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DiaMedica Therapeutics Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 1,955	\$ 2,156	\$ 3,929	\$ 4,562
General and administrative	1,409	1,209	2,971	2,422
Operating loss	(3,364)	(3,365)	(6,900)	(6,984)
Other income:				
Other income, net	13	98	48	102
Loss before income tax expense	(3,351)	(3,267)	(6,852)	(6,882)
Income tax expense	(7)	(7)	(14)	(14)
Net loss	(3,358)	(3,274)	(6,866)	(6,896)
Other comprehensive income (loss)				
Unrealized gain (loss) on marketable securities	(60)	—	(116)	1
Net loss and comprehensive loss	<u>\$ (3,418)</u>	<u>\$ (3,274)</u>	<u>\$ (6,982)</u>	<u>\$ (6,895)</u>
Basic and diluted net loss per share	<u>\$ (0.13)</u>	<u>\$ (0.17)</u>	<u>\$ (0.26)</u>	<u>\$ (0.37)</u>
Weighted average shares outstanding – basic and diluted	<u>26,443,067</u>	<u>18,786,157</u>	<u>26,443,067</u>	<u>18,776,461</u>

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,062	\$ 4,707
Marketable securities	35,381	40,405
Amounts receivable	88	130
Deposits	108	113
Prepaid expenses and other assets	534	84
Total current assets	<u>39,173</u>	<u>45,439</u>
Non-current assets:		
Property and equipment, net	74	70
Operating lease right-of-use asset	11	42
Total non-current assets	<u>85</u>	<u>112</u>
Total assets	<u>\$ 39,258</u>	<u>\$ 45,551</u>
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	\$ 624	\$ 509
Accrued liabilities	894	966
Finance lease obligation	7	4
Operating lease obligation	11	45
Total current liabilities	<u>1,536</u>	<u>1,524</u>
Non-current liabilities:		
Finance lease obligation, non-current	7	3
Total non-current liabilities	<u>7</u>	<u>3</u>
Shareholders' equity:		
Common shares, no par value; unlimited authorized; 26,443,067 shares issued and outstanding as of June 30, 2022 and December 31, 2021		
	—	—
Paid-in capital	127,249	126,576
Accumulated other comprehensive loss	(167)	(51)
Accumulated deficit	(89,367)	(82,501)
Total shareholders' equity	<u>37,715</u>	<u>44,024</u>
Total liabilities and shareholders' equity	<u>\$ 39,258</u>	<u>\$ 45,551</u>

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

	Six Months Ended June 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (6,866)	\$ (6,896)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation	673	957
Amortization of premium on marketable securities	160	38
Non-cash lease expense	31	28
Depreciation	12	12
Changes in operating assets and liabilities:		
Amounts receivable	42	324
Deposits	5	6
Prepaid expenses and other assets	(450)	(250)
Accounts payable	115	(860)
Accrued liabilities	(106)	239
Net cash used in operating activities	<u>(6,384)</u>	<u>(6,402)</u>
Cash flows from investing activities:		
Purchase of marketable securities	(27,510)	(25,244)
Maturities of marketable securities	32,258	26,235
Purchases of property and equipment	(6)	(13)
Proceeds from disposition of property and equipment	—	2
Net cash provided by investing activities	<u>4,742</u>	<u>980</u>
Cash flows from financing activities:		
Proceeds from the exercise of stock options	—	244
Principal payments on finance lease obligations	(3)	(3)
Net cash provided by (used in) financing activities	<u>(3)</u>	<u>241</u>
Net decrease in cash and cash equivalents	(1,645)	(5,181)
Cash and cash equivalents at beginning of period	4,707	7,409
Cash and cash equivalents at end of period	<u>\$ 3,062</u>	<u>\$ 2,228</u>
Supplemental disclosure of non-cash transactions:		
Assets acquired under financing lease	<u>\$ 10</u>	<u>\$ —</u>